Aiding Lower-limb Amputees in Traversing Uneven Terrain Through Product Design

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Aiding Lower-limb Amputees in Traversing Uneven Terrain Through Product Design

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SUMMARY

Most lower-limb amputees in the US today did not become amputees due to a congenital disease or a traumatic occurrence in their life. The leading cause of lower-limb amputations is due to diabetes and more specifically, Type 2 diabetes. Type 2 diabetes usually occurs in over-weight, middle-aged adults who lead a sedentary lifestyle and maintain a high-calorie diet. For some Type 2 diabetics, an amputation is an unfortunate result of the life-style they chose to lead. However, for many, an amputation becomes a wake-up call of sorts and makes them realize they must make drastic changes in their lives if they want to continue living them. Despite the fact that they want to change their lifestyle, this is something that is easier said than done.

Activities such as running, bicycling, rock climbing, or golfing usually require a specialized prosthesis or accessory in order to perform that task. However, there is one large barrier that can stand in the patient's way of performing that task. The main barrier these patients face is cost. Many patients rely solely on Medicare or Medicaid to cover the costs of the prosthesis, which is only $2,500 to $5,000. This means that despite the fact these patients wish to better themselves and their lives by becoming more active, they cannot because they cannot afford the specialized equipment needed to perform those activities. A solution must be discovered in order to solve the issue of high costs for prosthetic devices that will allow lower-limb amputees to perform the activities they wish to perform.

This thesis aims to add to the current state of knowledge concerning lower-limb amputees and the activities they wish to perform, identifying the barriers that keep them from performing an activity, and designing a low-cost device that allows them to better perform an activity.

CHAPTER 1

INTRODUCTION

Industrial Design can be defined in a variety of ways. It can be interpreted as a form of art, a particular process, a style of thinking, or simply as a profession. Whatever definition of industrial design one adheres to, one thing is common throughout and that is problem solving. Whether the problem is how to make something more aesthetically pleasing, manufacture a product more efficiently, or increase the usability of a system, all are examples centered on solving a particular problem. Given this fact, an industrial designer can take a look at the world around them and see a wide array of problems that need solving. Some big, some small, but all can benefit from the thought process and skills that an industrial designer can bring to the table.

Industrial designers acquire a lot of inspiration from problems they encounter on a daily basis. However, these problems do not need to be directly happening to them. In fact, the majority of the time it is a problem they observe happening to someone else, and it leads the designer to think, “How can I improve upon that?” One such observation came from having many conversations with a close colleague and friend who is an above-knee amputee and also happens to be a prosthetist. These conversations were centered on the problems lower-limb amputees face on a daily basis; however, the subject of cost was a reoccurring theme for a variety of the problems and seemed to be the user’s biggest barrier. In order for lower-limb amputees to maintain a healthy lifestyle after the amputation, some have to become more active than they were prior to their amputation. This is where the barrier of cost comes into play, as many cannot afford the astronomical prices that are associated with prostheses that allow them to perform certain physical activities.

Within the amputee community, there is one cohort of people who have a great need for a cost-effective prosthesis that will allow them to perform certain physical activities. This cohort is a lower-limb amputee over the age of 45 who received an amputation due to a vascular disease resulting from complications from diabetes. Many of these patients are Type 2 Diabetics, meaning they received their amputation after leading a sedentary lifestyle and having a poor diet [3]. For many, their amputation is a wake-up call of sorts and is motivation for them to change their lifestyle. However, due to the high-costs associated with specialized prostheses that allow lower-limb amputees to perform certain activities, many are limited to a prostheses that only covers their basic walking needs. Through alternative methods of design and manufacturing, there is an opportunity to develop a cost-effective device that will aid this cohort of people in performing physical activities.

Purpose and Contribution

The purpose of this thesis is to develop a cost-effective device that aids lower-limb amputees in performing an activity. In the process of reaching this goal, the current state of knowledge concerning which activities lower-limb amputees wish to perform and which specific barriers deter lower-limb amputees from performing those activities will be added to.

CHAPTER 2

LITERATURE REVIEW

In order to design a cost-effective device for lower-limb amputees that will aid them in performing an activity, one has to become knowledgeable in a wide breadth of subject matter. One area to examine is the current state of prosthetics in terms of market, user makeup, and manufacturing. According to a study done by Global Industry Analysts, Inc. in 2011, “The global orthopedic prosthetics market is projected to reach US$19.4 billion by the year 2015, led by an aging global population, rising incidence of degenerative joint diseases such as osteoporosis and arthritis, and the desire for maintaining active lifestyles”[1]. After looking more closely at the amputee population, it becomes evident that one of the leading causes for people to undergo a lower-limb amputation is diabetes [2]. Type 2 Diabetes, the most common form of diabetes, typically develops in middle-aged, older, overweight adults. Many of these Type 2 diabetics developed their condition due to a lack of activity and a poor diet [3]. However, once the extreme measure of having to amputate one’s limb is taken, it can be a wake-up call for the patients. During an interview with a prosthetist named Josh McNeil from Forroux Prosthetics in Huntsville, Alabama, he explained, “What I see in the clinic is that there is a percentage of these individuals who get shaken up enough because of the amputation that they begin to change their lifestyle.” Despite the fact that patients want to turn their lives around after undergoing an amputation, there is still a large hurdle that remains: cost [4]. Many people do not have access to the specialized prosthesis required for activities such as running, bicycling, golfing, or hiking. Rather, many patients have to rely on insurance that only covers, “in the range of $2,500 to $5,000 a year” for all their prosthetics [5]. This amount is only enough to cover the user’s basic needs for walking and nothing more. Josh McNeil agrees that “…when the individual wants to become more active they almost always see that their current set up is inadequate for the activity they are trying to complete.” If patients are not able to afford the necessary equipment they need to overcome the sedentary lifestyle that led to the amputation in the first place, then their options become greatly limited in how they can overcome this hurdle. In order to understand why prostheses are so costly, one must understand the manufacturing process and the amount of labor that goes into making one.

The biggest reason prostheses are so costly is that each one is unique to the user. While most prostheses are comprised of the same components and materials, each one must be custom fit to the user and his/her specific needs. Prostheses for lower-limb amputees are comprised of three main components: the socket, the leg, and the foot. The socket is what links the user’s body with the prosthesis. The process of creating one of these sockets is time consuming, labor intensive, and again, costly. In regard to the leg itself, without insurance, the prosthesis can range in price anywhere from $5,000 for a basic leg, all the way up to $70,000 for a computerized prosthesis [6]. A high-end prosthetic foot can cost upwards of $5,000 [7]. Given the high-costs of prosthetics, there is an opportunity to design a better prosthetic device with more cost-effective manufacturing methods in mind. In order to gain perspective on cost-effective prostheses that exist today, one avenue to explore is prostheses for the developing world.

Prostheses in the developing world are cost-effective out of necessity. Many war-torn and poverty-stricken countries sometimes have to rely on the resourcefulness of their people and the materials available in order to create prosthetic devices. The Jaipur Foot is one such example of this resourcefulness. Many prosthetics created for the Western world did not accommodate the barefoot lifestyle of many amputees in the Indian city of Jaipur. A local orthopedist named Professor P. K. Sethi recognized this problem and developed a foot made from locally sourced materials that could be built by local craftsmen in under an hour for about 250 Indian Rupees or $3.94 [8]. Another example of a cost effective prosthesis for the developing world is the Niagara Foot. Again, the main driving force behind the design of this foot was cost. However, unlike the Jaipur foot, modern manufacturing methods were used to produce this foot via injection molding for a cost of under $100 [9]. What made the Niagara Foot unique was the simplicity of its design and it was this simplicity that allowed the foot to be manufactured for such a low cost.

The idea of utilizing simple designs as a method of reducing costs is another avenue worth exploring. Simple designs are cost-effective by nature because normally fewer parts are used; assembly and manufacturing are less complex; and fewer types of materials are used. One example of a simplistically designed prosthesis was developed by a group of MIT students in 2014. The design utilized modularity and medical grade plastics to create a cost-effective prosthesis [10]. The modularity aspect of the design made it simplistic because parts for prosthetic legs could be used for prosthetics arms and vise versa. By looking at examples of prostheses made for the developing world and ones that utilize more simplistic designs, it is apparent that not only manufacturing, but materials as well must be considered when developing a cost-effective prosthesis. One approach to improving both the manufacturability and material costs of creating a prosthesis is 3D printing.

There are cases of amputees creating their own 3D printed prosthetic hands and using them on a day-to- day basis. For example, when a South African carpenter named Richard Van As found that it would cost him nearly $20,000 dollars to replace two fingers from an accident he had while working, he began looking into creating his own prosthetic fingers and apparatus. He came across a theatrical prop designer named Ivan Owen, who created a 3D printed hand in 2011 for a young child [11]. Van As and Owen were able to develop a prosthesis for only $150 [12]. A Colorado teenager was able to create a fully functional and organically shaped prosthetic arm for $500 only using 3D printed parts [13] The material used for these applications was ABS plastic, a relatively strong and durable plastic. However, ABS is not strong enough for prosthetic devices for lower limb amputees, as evidenced by a preliminary investigation done in 2005 in Scotland. Researchers found that it is indeed possible to create a comfortable prosthetic socket for lower-limb amputees using 3D printing technologies, but the sockets fell short in strength and durability [14]. Bespoke Innovations created an entire prosthetic leg, including the knee, foot, and socket using only a 3D printer [15]. While this leg was able to be worn comfortably and be walked upon, it was not as strong and durable as a traditional prosthetic leg.
It is clear that the material properties of 3D printed prosthetics are the main obstacle to their widespread use. In order for 3D printing to be feasible for manufacturing prostheses, lower-limb amputees must first use the prostheses created using these technologies. Furthermore, to be able to encourage lower-limb amputees to use these prostheses, one must understand the activities that amputees plan to do.

In 2001, the Department of Veterans Affairs conducted a study of lower-limb amputees to determine which activities are common amongst this cohort of people. The 10 most common activities listed were bowling, camping, dancing, fishing, gardening, golf, hunting, reading, walking, and woodworking. Given that this list of activities was extremely broad, the list was narrowed and segmented into different categories. The activities were divided into categories based on the level of energy required to perform a task, including high, moderate, low, or sedentary levels of energy. The results from this Department of Veterans Affairs survey show that most lower-limb amputees tend to perform activities in the moderate to low range, like camping, swimming, cooking, and fishing [16]. Setting up the groundwork in terms of the actual physical activities lower- limb amputees currently perform provides a more well informed line of questioning for end-users and professionals in the future.

After conducting research into lower-limb amputees, prosthetic manufacturing and design, alternative cost-effective manufacturing methods for prostheses, and what activities lower-limb amputees currently perform, a target user group has been established along with a problem area that exists within that group. The target user group is older, lower-limb amputees who received an amputation due to diabetes, brought on by a poor diet and a sedentary lifestyle. This group was chosen because for many, Medicare and Medicaid is the only way they can afford a basic prosthesis, yet those basic prostheses are inadequate in providing them with a means of performing the physical activities they need to perform. Given that cost is the biggest hurdle for this group of people, the final device needs to be cost-effective and something the user can pay for out-of-pocket. In order to accommodate this goal of cost-effectiveness, different avenues of production will be explored such as designs for the developing world, simplistic designs, and 3D printing.

CHAPTER 3

Discovery & Methods

The purpose of the literature review was to determine what information was needed to guide the research methodology and future design paths. The area of focus on older, diabetic, lower-limb amputees was selected, as they make up the highest percentage of lower-limb amputees. They were also selected because there is a need for a cost-effective device that allows them to perform outdoor activities, as it is necessary for older diabetic patients to become more active after receiving an amputation.

3.1 What outdoor activities do older amputees wish to perform?

In order to begin designing a device that will assist older, diabetic, lower-limb amputees in performing outdoor activities, one must first discover what activities they wish to perform. Approval from the Institutional Review Board (IRB) at the Georgia Institute of Technology was procured for this study prior to survey distribution. A survey was dispersed through various prosthetic manufacturers including Fourroux Prosthetics in Huntsville, Alabama and Hanger Prosthetics in Atlanta, Georgia. The survey was distributed on paper rather than electronically, as many of the subjects were older and potentially had limited access to or did not know how to properly use a computer and/or the Internet. By distributing the survey in person, subjects could ask questions and get clarification if needed. Despite that the target demographic for this study is 45 or older, anyone of any age could take the survey, with the only requirement being that the subject was a lower-limb amputee. The survey distributed in this phase of the research can be seen below in Figure 1.

Survey for 3D Printed Prosthetic Foot for Outdoor Activities

Objective: My name is Mark Husack and I am a Masters of Industrial Design student from the Georgia Institute of Technology in Atlanta, Ga. This survey will be used to determine the types of physical activity currently performed by lower-limb amputees. This survey will also help determine if there are any shortcomings in regards to an amputee's current prosthesis, most notably, shortcomings that prevent them from performing outdoor physical activities. By voluntarily participating in this survey, your identity will remain anonymous and confidential, as no personal information, other than your age and gender, will be given. If you choose to participate, you are free not to answer any of the given questions. If you have any questions, comments, or concerns about this study, feel free to contact me at husack.m@gmail.com or by telephone at (404) 626-0257. Thank you.

Age: ______
Gender: ______

1.) Are you an above or below knee amputee? (circle one)

a. Above-knee   b. Below-knee

2.) How long has it been since your amputation?

a. Less than 6 months   c. 1-3 years

b. 6 months-1 year   d. 3+ years

3.) For each activity listed below, please place a check mark indicating the most appropriate response:

	Basketball	Golfing	Walking	Bowling	Hunting	Hiking	Biking	Rock Climbing	Football	Fishing	Tennis	Camping
I participate regularly												
I participate occasionally												
I would like to participate but cannot due to an inadequate prosthesis												
I am not interested in this activity												

4.) Are there any activities NOT listed in question 3 that you perform or wish to perform? If so, please explain to what level you perform said activity.

5.) How much are you willing to pay out-of-pocket for a prosthetic foot designed for a specific activity?

a. $50-$100   c. $250-$500

b. $100-$250   d. $500 or more

Figure 1: Survey for 3D Printed Prosthetic Foot for Outdoor Activities

General information about each subject was gathered including age, gender, type of amputation, and how long it had been since their amputation. The type of amputation and length of time since amputation are important information to consider, because it can determine the way the subject ambulates and the experience level. A question concerning price point was also asked to determine what people are willing to pay "out-of-pocket" for a specialized prosthetic device that allows them to better perform an outdoor activity. However, the main focus of this survey was the third question, asking subjects what outdoor activities they wish to perform but cannot due to an inadequate prosthesis. The questionnaire also asked subjects if they already perform certain activities or if they have no interest in performing certain activities. The activities themselves were chosen based on a study done by the Department of Veterans Affairs [16]. However, in the Department of Veterans Affairs' study, the question was left open ended, and therefore, it produced a wider variety of responses. The activities chosen for this survey were based upon the percentage of responses given by the Department of Veterans Affairs survey and also by the varying levels energy required to perform those activities.

3.1.1 Survey Results and Conclusions

After collecting the completed surveys, the investigator received a total of 48 responses. The following conclusions can be derived from the results of this survey:

- The age distribution validates that found in the literature review (average age 51.79 years)
- The majority of respondents (58.3%) have had their amputation longer than 3 years
- The majority of respondents (60.4%) are willing to pay $250 or more "out-of-pocket" for a device that aids in performing a specific activity
- Hiking and biking are the two activities respondents stated they wish to perform but cannot due to an inadequate prosthesis.
- The results from Question 3 are show below in Figure 2.

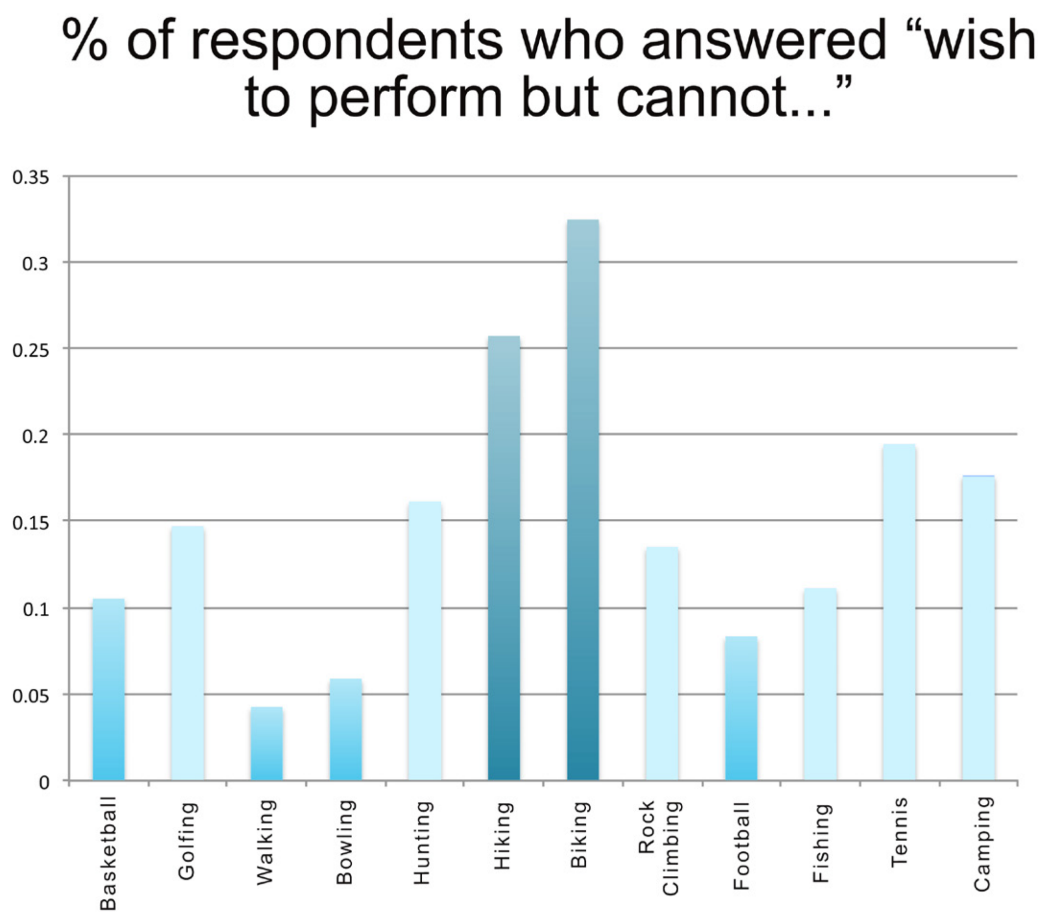


Figure 2: Percentage of Respondents Who Answered "I would like to participate but cannot due to an inadequate prosthesis"

The initial goal of this survey was to discover what activities lower-limb amputees wish to perform but cannot due to an inadequate prosthesis. However, a new question arose as to what specifically is limiting lower-limb amputees from performing these activities. To answer that question, professional prosthetists were asked to give their insights on the matter.

Approval from the IRB at Georgia Tech was procured for this study prior to any interviews being conducted. A total of five different prosthetists were asked a series of questions centered on what they would recommend to their patients if they wished to perform the outdoor activities of hiking and biking. The prosthetists were also asked what activities, in general, they recommend to their patients and how patients can go about achieving their goal of becoming more active. The full set of interview questions is below in Figure 3.

Interview Discussion Guide for 3D Printed Prosthetic Foot for Outdoor Activities

Interviews will be conducted both via email and phone. Before the interview begins, the interviewee will be made aware of what the study is about and what goals have been set at this point in the process. The goals are as follows:

- Determine if there is a need for a more widely available prosthetic foot, meant specifically for outdoor activities based upon their professional opinion.
- Discover if there are any shortcomings in terms of my approach to solving this problem.
- Narrow my overall focus in relation to my design methodology.

Once the goals and outline of the project have been presented to the interviewee, they will be asked if they have any initial questions. If they do not, they will be asked if they consent to be a participant in this interview. If they say yes, then interview will begin and if they say no, they will be thanked for their time and the interview will end.

The following is a set of sample questions to be asked to the various prosthetists:

- If a patient tells you they wish to hike as part of their rehab, what foot would you recommend?
- What activities do your patients tell you they regularly participate in?
- If a patient tells you they wish to hike as part of their rehab, but cannot afford a new prosthetic foot, what would you recommend they do to help them achieve their goal?
- Is wearing hiking boots or other kinds of footwear a simple solution for patients wishing to hike?
- Do you think that users could benefit from a completely individualized prosthetic foot attachment that is built from the ground up to allow the user to hike over uneven terrain?

Figure 3: Interview Discussion Guide

In interviewing the various prosthetists, they gave some interesting insights into the results from the previous survey. Many of the prosthetists felt that some of the data may have been misrepresented given how the questions were presented. The survey results indicated which activities lower-limb amputees wish to perform but cannot due to an inadequate prosthesis. However, according to the prosthetists interviewed, there is more behind the reasoning of why respondents answered this way. A lower-limb amputee who is able to ambulate on a regular basis without the use of a walking aid should be able to perform the activities of hiking and biking without the need for a specialized device. Josh McNeil of Fourroux Prosthetics said, “…you have to break fears, a lot of them are scared”, [17] indicating one reason these activities are not performed is an issue of confidence. Below are other insights gained from different prosthetists during the round of interviews:

“They need to be in better shape with their prosthesis than they were before they lost their limb” [18]

“There is a test to determine what k-level they are at and they can be reevaluated 6 months to a year down the road to determine if they have moved to a higher k-level. This test is a series of movements/activities (i.e. can they do it, do they need assistance, etc.) and a numerical value is assigned to each answer.” [19]

“I don’t encourage them necessarily; I am just giving them the tools. Something that limits the barriers...” [20]]

This idea of barriers to the end-user became a cornerstone of the next portion of the discovery phase. In order to narrow the focus of the design, these purported “barriers” must be further explored. Therefore, a second survey was created that specifically asked respondents what barriers they perceived when performing the activities of hiking and biking, discussed next in Section 3.4.

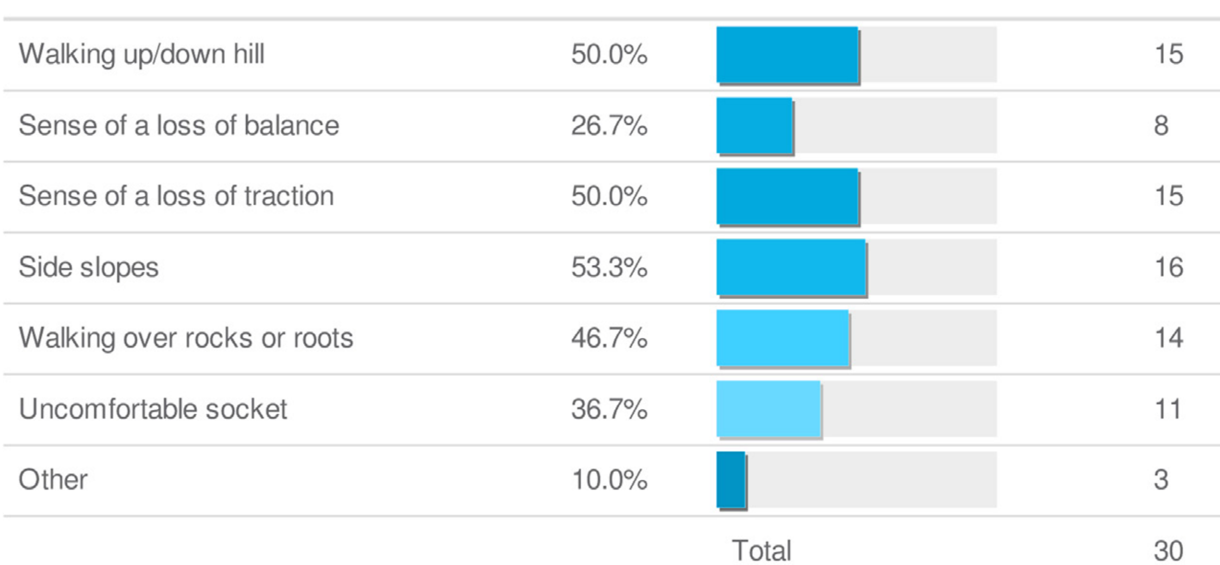
3.4 Survey for Hiking and Biking Barriers for Lower-limb Amputees

Approval from the IRB at Georgia Tech was procured for this protocol amendment prior to any survey distribution. The second survey set out to discover if lower-limb amputees currently bike or hike as a form of physical activity and, if so, what specific barriers or limitations they face when performing these activities. If respondents said they had no interest in these activities, they were asked why they felt this way and if motivation was a factor in this decision. The survey was titled “Hiking and Biking Barriers for Lower-limb Amputees” and was distributed online via a commercial survey tool. A total of 52 responses were received, with 13 partial and 39 complete responses. Some results for each question may vary as a response was not required for each question. The results are presented next in Section 3.4.1. A copy of the survey can be found in Appendix A.

3.4.1 Hiking and Biking Barriers Survey Results and Conclusions

The following conclusions can be drawn from the survey results concerning hiking:

- 48% of respondents were over the age of 45, fitting the target demographic
- Hiking is an activity 100% of respondents have an interest in performing, and a majority (82.1%) currently hike using their everyday prosthesis
- The primary barriers faced by lower-limb amputees while hiking are:
    - Walking up and down hill
    - Sense of a loss of traction
    - Side slopes
    - Walking over rocks and roots
- Lower-limb amputees see a need for:
    - A prosthetic foot specifically designed for walking over uneven terrain
    - A device that improves the fit and function of commercial hiking boots when worn by amputees



	A prosthetic foot designed for walking on uneven terrain	A device that improves the fit and function of commercial hiking boots when worn by amputees	A special boot or shoe designed to be used with a prosthesis
Yes, I see a need	**22** 66.7%	**10** 37.0%	**11** 35.5%
Yes, I see a need, but not for me	**6** 18.2%	**8** 29.6%	**9** 29.0%
No, I do not see a need	**5** 15.2%	**9** 33.3%	**11** 35.5%
Responses	**33**	**27**	**31**

Figure 4: Results from *"Survey for Hiking and Biking Barriers for Lower-limb Amputees"*, Hiking portion.

The following conclusions can be drawn from the survey results concerning biking:

- Biking is an activity 89.7% of respondents have an interest in performing, and 54.3% currently bike using their everyday prosthesis.
- The primary barriers faced by lower-limb amputees while biking are
  - Securing prosthetic foot to the pedal
  - Mounting the bike
- Lower-limb amputees see a need for
  - A clip that secures the prosthetic foot to the pedal
  - A prosthetic leg meant specifically for biking

Mounting the bike	31.6%	6
Securing prosthetic foot to the pedal	63.2%	12
Socket discomfort	26.3%	5
Poor balance on the bike	15.8%	3
Other	31.6%	6
	Total	19

	A clip that secures your prosthetic foot to the pedal	A bicycle built specifically for lower-limb amputees	A prosthetic leg meant specifically for biking
Yes, I see a need	**13** 72.2%	**7** 41.2%	**8** 50.0%
Yes, I see a need, but not for me	**2** 11.1%	**4** 23.5%	**5** 31.3%
No, I do not see a need	**3** 16.7%	**6** 35.3%	**3** 18.8%
Responses	**18**	**17**	**16**

Figure 5: Results from *"Survey for Hiking and Biking Barriers for Lower-limb Amputees"*, Biking portion

It can be concluded from these survey results that the activity of hiking or walking over uneven terrain should be the area of focus for further investigation as 100% of respondents reported that they have an interest in hiking and 82.1% said they already perform this activity. This is compared to the 89.7% of respondents who stated they have an interest in biking and 54.3% who say they already do. Because 100% of respondents stated they have an interest in hiking or walking over uneven terrain as a form of physical activity and that there were more responses to the question regarding specific barriers related to hiking than there were for specific barriers related to biking, there is a greater opportunity gap to be filled in developing a device for hiking as compared to biking. With the concept direction established, concept development could begin.

3.5 Concept Development

3.5.1 Weighted Matrix

When exploring possible solutions to the issue of providing lower-limb amputees with a cost-effective means to more easily perform the activity of hiking or walking over uneven terrain, there are three main avenues to investigate:

- A prosthetic foot designed for walking on uneven terrain
- A device that improves the fit and function of commercial hiking boots or walking shoes
- A special boot or shoe designed to be used with a prosthesis

The following question was asked of lower-limb amputees in the previous survey in terms of which they felt was a more viable solution. The results are as follows:

	A prosthetic foot designed for walking on uneven terrain	A device that improves the fit and function of commercial hiking boots when worn by amputees	A special boot or shoe designed to be used with a prosthesis
Yes, I see a need	**22** 66.7%	**10** 37.0%	**11** 35.5%
Yes, I see a need, but not for me	**6** 18.2%	**8** 29.6%	**9** 29.0%
No, I do not see a need	**5** 15.2%	**9** 33.3%	**11** 35.5%
Responses	**33**	**27**	**31**

Figure 6: Results from *"Survey for Hiking and Biking Barriers for Lower-limb Amputees"*, Hiking portion, Question 9

From these results, it can be derived that all three options warranted further exploration. Despite the fact a majority of respondents saw a need for a specially designed prosthetic foot, the other two options gained enough positive responses that they warranted further exploration. One tool to facilitate the further exploration of these concepts is a weighted matrix. A weighted matrix compares the design criteria against different concepts by assigning levels of importance, or weight, to the criteria and levels of value in relation to that criterion for the concepts. The results found in Figure 6 do not factor in to the weights and values of the weighted matrix as the individual concepts are being evaluated on different criteria than what was asked in that question. The design criteria to be weighted against the concepts are manufacturability, perceived efficacy, and perceived usability. Manufacturability essentially means how cost-effective something is to produce. Perceived Usability can be defined as how easy the concept is to use for the end-user. Perceived Efficacy is how effective the concept is at performing the desired task. The value assigned to each concept will be determined through a different method for each criterion. Manufacturability values will be determined by comparing each concept to current products available on the market (i.e., compare costs of other prosthetic devices that perform these same functions). Perceived Usability values will be determined using information gathered from interviews with prosthetists and in talking with lower-limb amputees about the process involved when one dons and doffs their prosthesis. Perceived Efficacy values was also determined by comparing each concept to current products available on the market. The weights associated with these design criteria were derived from interviews with prosthetists after the first round of surveys and also from the comment sections in the 2nd survey. By utilizing information directly from end-users and professionals in the field, accurate weights were able to be ascertained. The weighted matrix is shown in Figure 7.

Design Criteria

Concepts	Manufacturability Weight: 9		Perceived Usability Weight: 8		Perceived Efficacy Weight: 5		TOTALS
	Value	Total	Value	Total	Value	Total	
A prosthetic foot designed for walking on uneven terrain	2	**18**	1	**8**	4	**20**	**46**
A device that improves the fit and function of common hiking boots or walking shoes	4	**36**	3	**24**	3	**15**	**75**
A special boot or shoe designed to be used with a prosthesis	2	**18**	3	**24**	3	**15**	**57**

Manufacturability: Design for manufacture; is the concept cost-effective to produce?
Perceived Usability: Is the concept easy to use?
Perceived Efficacy: How effective is the concept at performing task?
Weight: Scale of 1-10; 10 = most important, 1 = least important
Value: Scale of 1-5; 5 = most valuable, 1 = least valuable

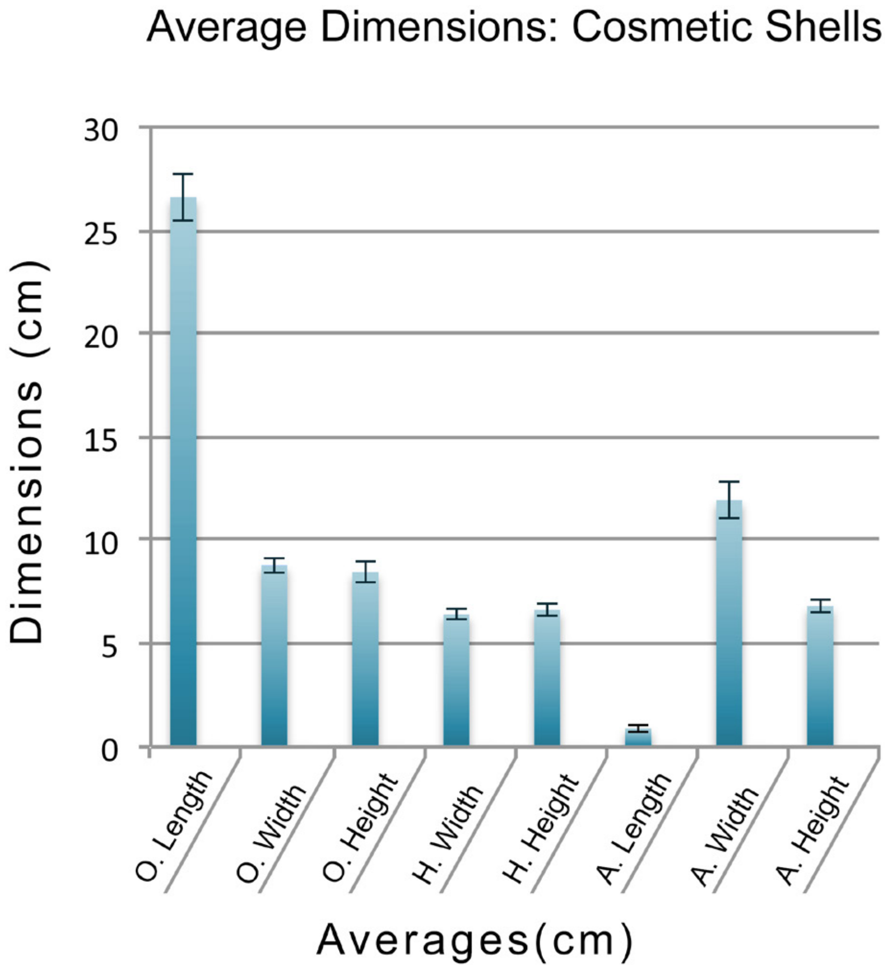
Figure 7: Results from Weighted Design Matrix

3.5.2 Two Disparate Directions and Why

The weighted matrix in Figure 7 shows that a device that improves the fit and function of commercial hiking boots or walking shoes and a special boot or shoe designed to be used with a prosthesis are the concepts to be further explored. One reason the concept of a prosthetic foot designed for walking on uneven terrain was excluded here is due to the complexities associated with manufacturing, in addition to its low perceived usability due to the fact that a prosthetist must be involved in order to fit the patient with the device. With the two chosen concept directions, users are able to decide on their own whether or not they want to use the device when they wish. This idea of “spontaneity of use” is very important to the overall design goal because it reduces the barriers lower-limb amputees face when considering hiking or walking over uneven terrain as a form of physical activity. Also, the two chosen concept directions are improving on the existing prosthesis rather than trying to create an entirely new one.

3.5.3 Cosmetic Shell Dimensions

Due to the fact that both chosen concept directions are centered on improving the function of the existing prosthesis, current prosthetic equipment must be analyzed. Specifically, the cosmetic shell that surrounds the prosthetic foot needs to be examined more closely, as it is the direct interface with the footwear and the prosthesis. To accomplish this, 20 different cosmetic shells ranging is size from 24cm for a 100 pound individual to 31cm for a 250+ pound individual were analyzed in terms of function and dimensions, as shown in Figure 8.



O. Width: Overall Width
H. Width: Heel Width
A. Width: Arch Width

Figure 8: Images of different cosmetic shells and dimensioning results with averages and variances included

By studying these cosmetic shells, one can determine the appropriate dimensions for future designs and also how these cosmetic shells function in terms of flexibility and fit of the prosthetic foot. However, in order to better understand the true functionality of these cosmetic shells, one must view them in action. To facilitate this, a group of amputees was gathered to go hiking in the mountains near Greenville, South Carolina. The observations from this excursion are presented next in Section 3.5.4.

3.5.4 Observations of Amputees Hiking

Hunter Scott, a lower-limb amputee and prosthetist with Boland Prosthetic and Orthotic Center assisted in organizing a group of amputees to go hiking in Paris Mountain State Park in Greenville, South Carolina [21]. The group consisted of a total of three amputees, with one being an above-knee amputee, one a below-knee amputee, and one a bilateral below-knee amputee. All of the participants worked in the prosthetic manufacturing industry, and as such, were well informed and well experienced with prosthetics. The area of Paris Mountain State Park offered a wide variety of terrain to traverse with side slopes, hills, loose soil, and plenty of obstacles to overcome such as rocks, tree roots, and holes. Photos depicting this observation session are shown in Figure 9.

Figure9: Observation photographs while hiking in Greenville, SC

Before the group began hiking, the amputee participants made some adjustments to their prostheses, such as checking the suction of the socket, tightening of bolts and screws where necessary, and ensuring their footwear was tight. It was this last observation, however, that was particularly interesting. It was noted that the participants were tying the shoe on their prosthetic foot significantly tighter than they were on their actual foot. Upon further questioning as to why this is, it was discovered that this is what the participants do with most of their footwear and not just when hiking. It was stated by one participant that despite the cosmetic shell and size of their shoe being equitable, the cosmetic shell still did fill in the shoe as well as their normal foot did. It was also stated by the same participant that other than tying the shoe on the prosthetic foot extra tight, they sometimes stuff extra socks or other fabric into the shoe to create a better fit. After a day of hiking and talking with the participants, it became more apparent that there is an opportunity to develop both concept directions and investigate them further.

3.5.5 Iterations

Now that the concept directions were established and validated with survey data, a weighted design matrix, and observations, design iterations were created.

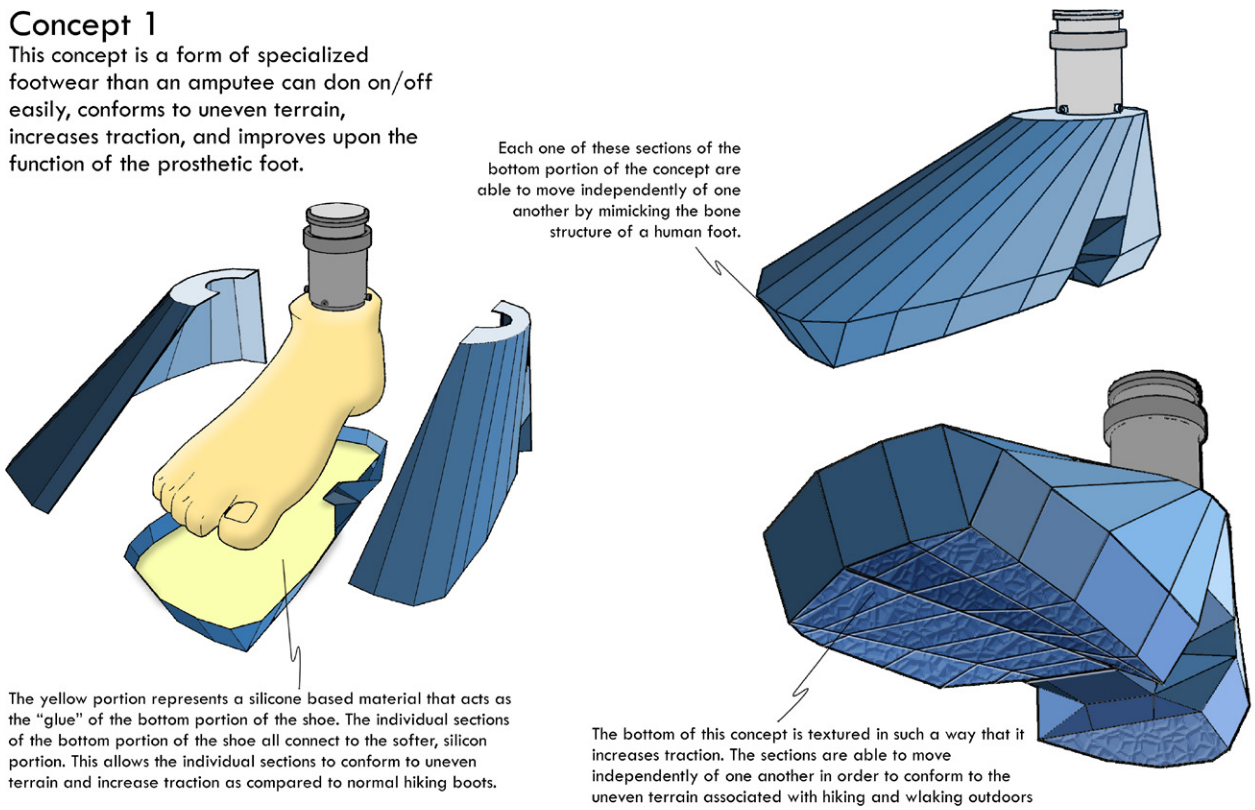


Figure 10: First round of designs for foot shroud concept

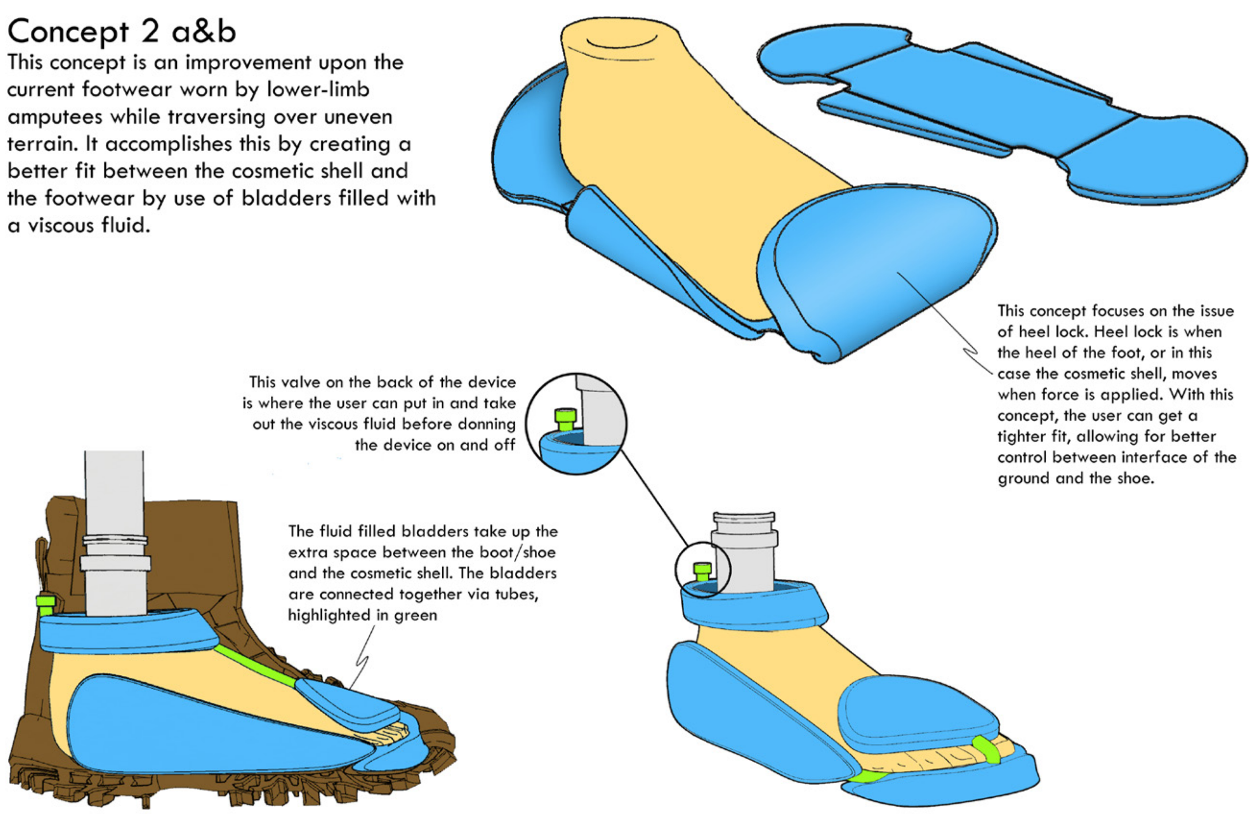


Figure 11: First round of designs for bladder concept

The focus of these first two designs was creating a better fitting shoe while not hindering the functionality of the prosthetic foot and cosmetic shell. The first concept, the foot shroud, is manufactured via 3D printing and is able to be customized to the individual's specific cosmetic shell. The second concept, the bladder, fills in the voids within the footwear of the user, creating a better fitting shoe and in turn, allowing for greater control and confidence while traversing uneven terrain. Both concepts were presented to Dr. Katherine Fu, an industrial design and mechanical engineering professor, for feedback and the following questions were raised:

Foot Shroud Concept
- How are the faceted (blue) pieces attached to one another to enable movement?
- How will you ensure that the shoe stays on the foot in a stable way?

Bladder Concept
- Does the user have to fill and un-fill the bladder each time they use it?
- How would the user get this into the boot?
- How would they make sure their foot was positioned properly among the bladders and within the boot?

Given this feedback, refinements were made to each concept and a new set of designs was created.

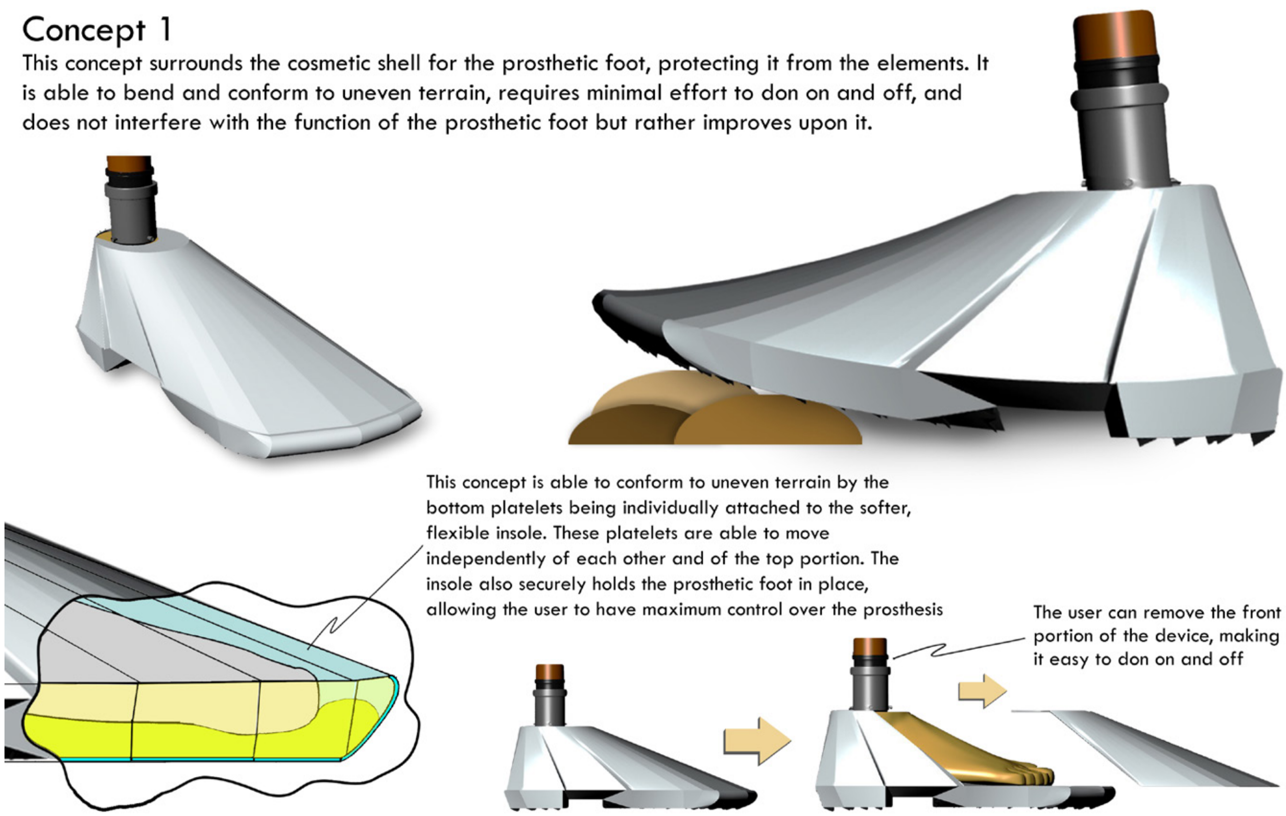


Figure 12: Second iteration of foot shroud concept

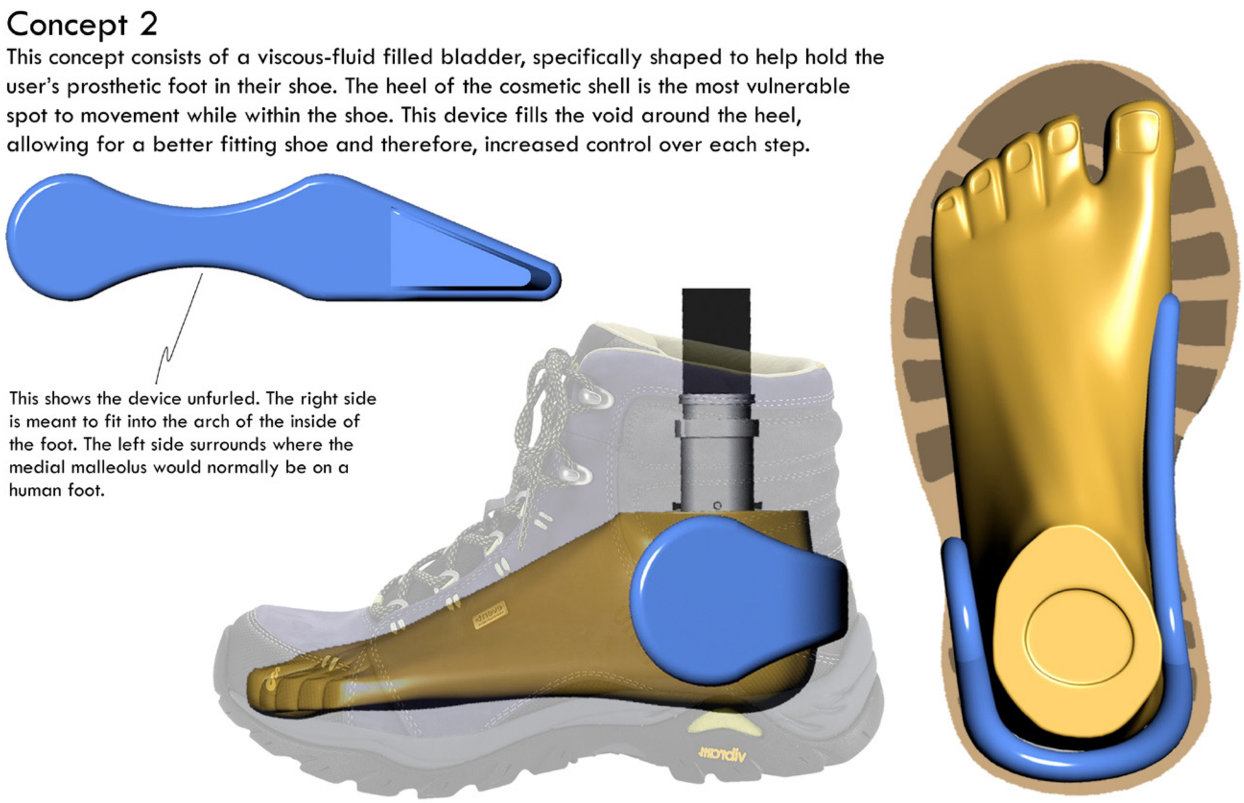


Figure 13: Second iteration of bladder concept

Both concepts were again presented to Dr. Fu for feedback and the following questions were raised:

Foot Shroud Concept
- Users may ask you what makes this better than a hiking boot?
- The deformation of the sole portion will be limited by the rigidity of the foot itself

Bladder Concept
- Do they (the user) put it on the foot and then put both inside the shoe?
- What is the process for the user?
- Do you need to change anything about the design to make that process as easy as possible?

The designs were also presented to various prosthetists to gain their professional opinion. The important pieces of feedback received from the prosthetists are as follows:

Foot Shroud Concept
- "More flex needed, the less rigid the better."
  Daniel Cloy, Marketing Director at
  Advanced Prosthetics

- "Parts and pieces are a concern for the shroud. Anytime you have different pieces it could cause creaking; things can pop off, etc."
  Rob Kistenberg, Prosthetics Coordinator at
  Georgia Institute of Technology

- "The shell is really cool and could be built on, but would be hard to manufacture"
  Josh McNeil, Certified/Licensed Prosthetist at
  Fourroux Prosthetics

Bladder Concept

- “You’ll have to unlace your foot a lot anyway when putting on almost any shoe. This concept is a lot more feasible, no moving parts, simpler.”
  Daniel Cloy, Marketing Director at
  Advanced Prosthetics [22]

- “If the bladder could be deflated and inflated, it would be better. Could be hard to get their foot in and out.”
  Rob Kistenberg, Prosthetics Coordinator at
  Georgia Institute of Technology [23]

- “It fills in the spots that are most vulnerable to where the shoes fits.”
  Josh McNeil, Certified/Licensed Prosthetist at
  Fourroux Prosthetics [24]

After reviewing the feedback gained from both Dr. Fu and the various prosthetists, a final round of designs was created that addressed the collective concerns of the group.

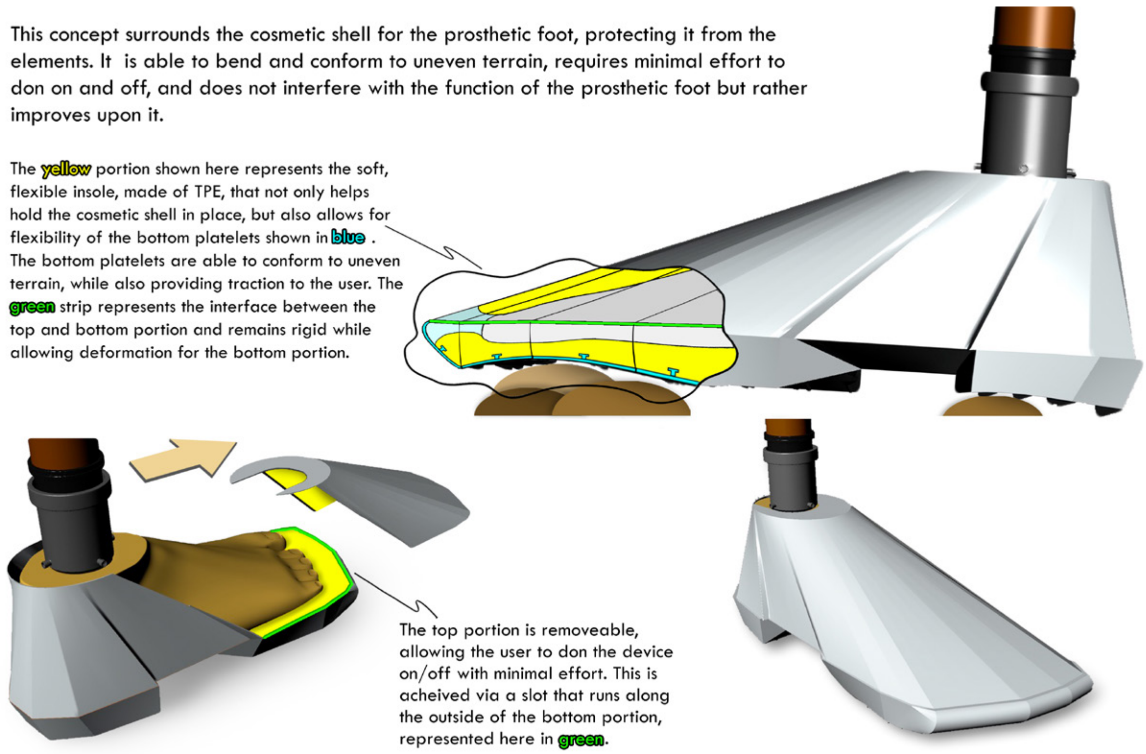


Figure 14: Third iteration of foot shroud concept

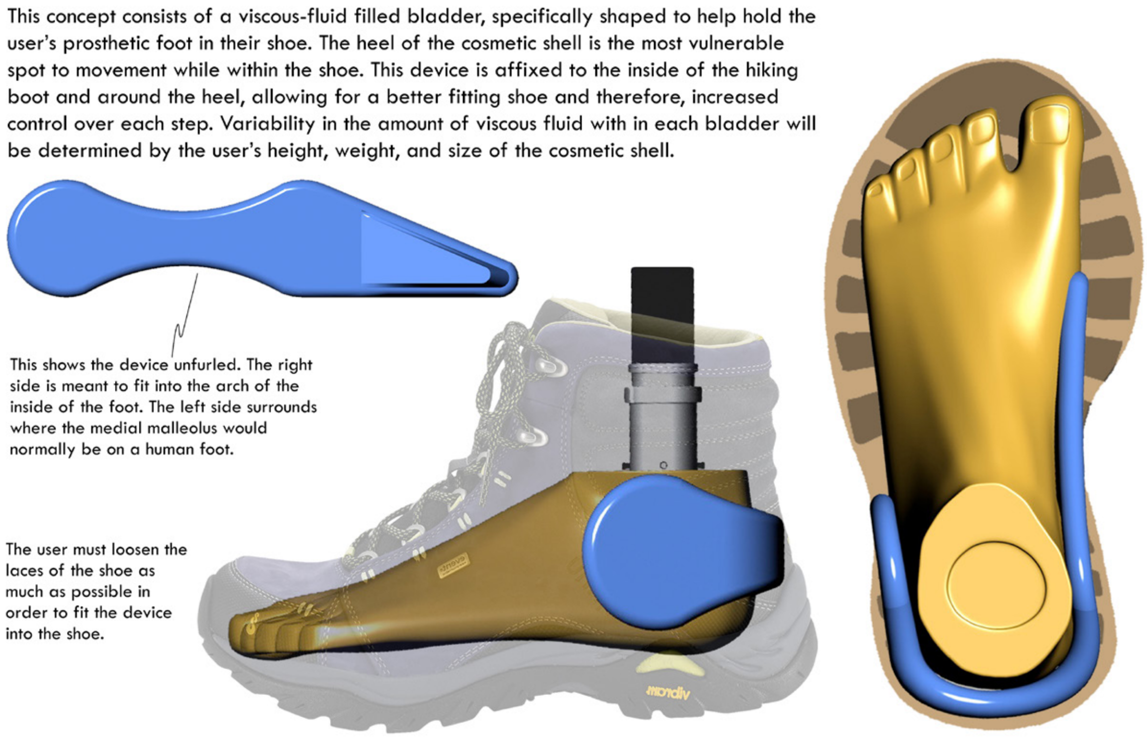


Figure 15: Third iteration of bladder concept

3.6 Survey for Hiking Prototypes for Lower-limb Amputees

The third survey set out to discover what opinions lower-limb amputees had on the two concept directions and the designs that were generated from them. The survey was titled “Hiking Prototypes for Lower-limb Amputees” and was distributed online via a commercial survey tool a total of 124 responses were received with 56 partial and 68 complete responses. The results are presented next in Section 3.6.1. A copy of the survey can be found in Appendix B.

3.6.1 User Feedback Survey Results and Conclusions

Regularly	58.8%	40
Occasionally	29.4%	20
Rarely	7.4%	5
Never	4.4%	3
	Total	68

Figure 16a: Results for how often subjects traverse uneven terrain

Very Active (running, high activity sports)	17.7%		12
Somewhat Active (moderate jogging)	35.3%		24
Not very active (walking only)	39.7%		27
No activity (do not walk)	7.4%		5
		Total	68

Figure 16b: Results for how active respondents are

The following conclusions can be drawn from the survey results:

- 49.3% of respondents were over the age of 45, fitting the target demographic
- 75% of respondents said they are either somewhat active (moderate jogging) or not very active (walking only), demonstrating that a large majority of the amputee population has a potential need for one of the concepts
- 88.2% of respondents said they either occasionally or regularly walk on uneven terrain, demonstrating a large majority of the amputee population has a potential need for one of the concepts

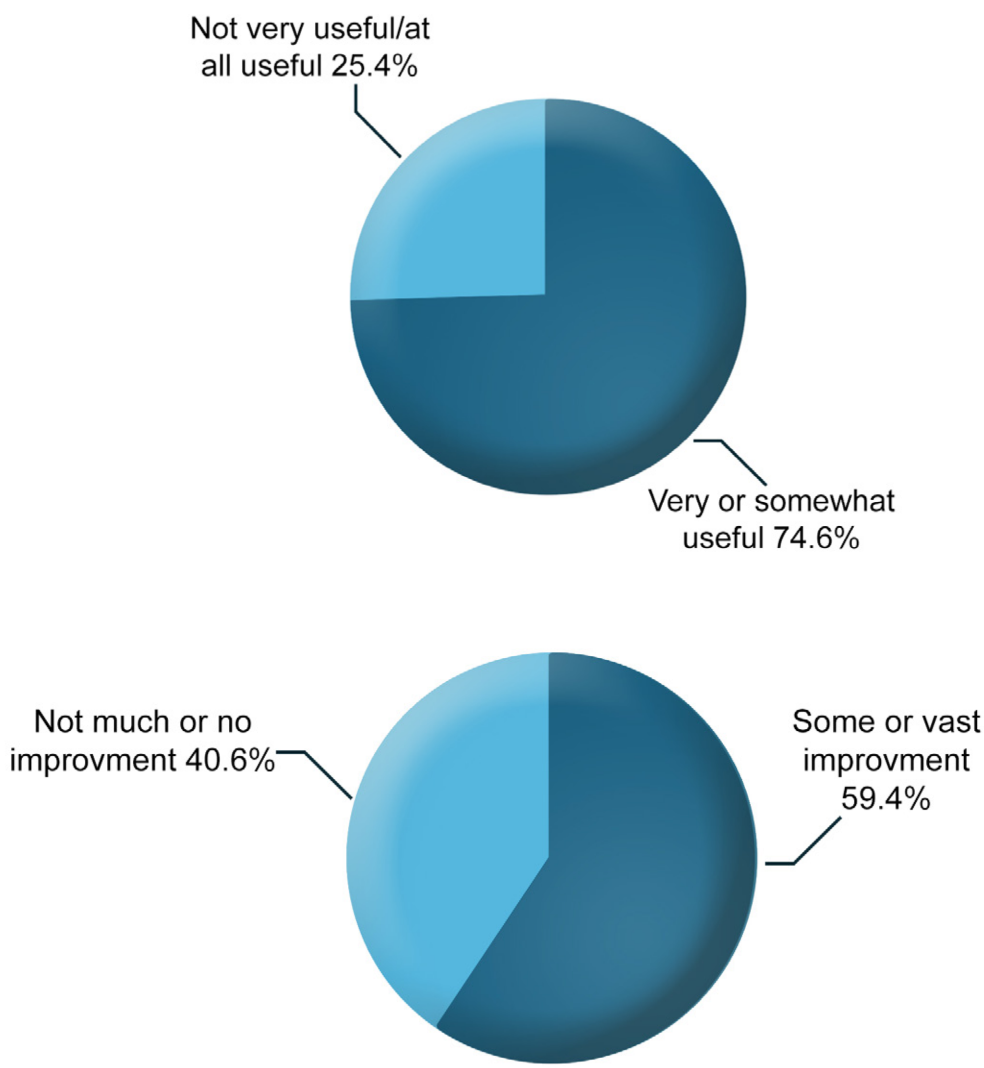


Figure 17: Results from survey questions concerning the foot shroud concept as to whether the concept was perceived as being useful (top) and if the concept demonstrates improvement compared to what is currently available (bottom)

Foot Shroud Concept

- 74.6% of respondents said they perceived this concept as being either somewhat useful or very useful for hiking or walking over uneven terrain
- 59.4% of respondents said they perceived this concept as having either some improvement or vast improvement compared to what is currently available for traversing uneven terrain

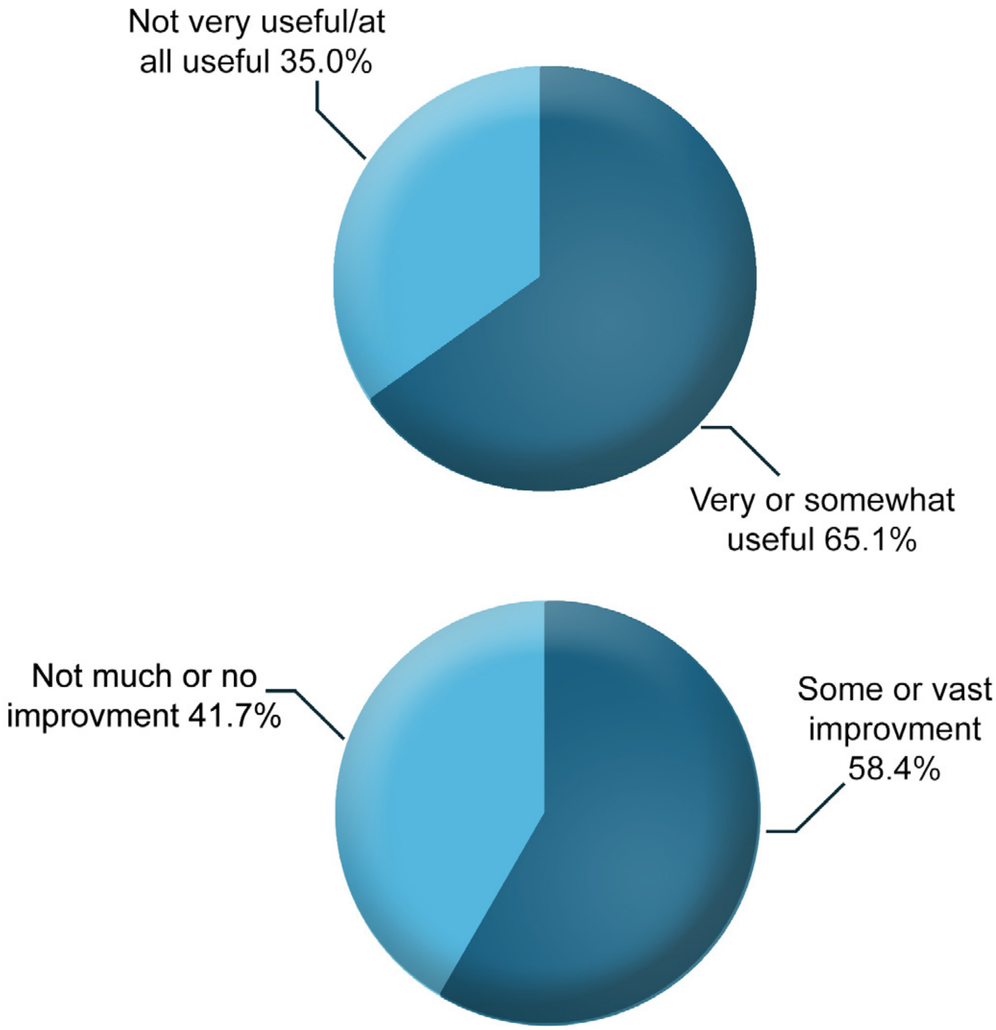


Figure 18: Results from survey questions concerning the bladder concept as to whether the concept was perceived as being useful (top) and if the concept demonstrates improvement compared to what is currently available (bottom)

Bladder Concept

- 65.1 % of respondents said they perceived this concept as being either somewhat useful or very useful for hiking or walking over uneven terrain
- 58.4% of respondents said they perceived this concept as having either some improvement or vast improvement compared to what is currently available for traversing uneven terrain

It can be concluded from these survey results that both concepts are equally valuable in the eyes of the end-user. Nearly 3 out of 4 respondents stated they saw value in the foot shroud concept and nearly 2 out of 3 saw value in the bladder system concept. Also, the majority of respondents felt both concepts were improvements compared to what is currently available for amputees to traverse uneven terrain. Further validation that both concepts are equally valuable in the eyes of the end user can be given by using McNemar's Test. McNemar's Test was chosen because it accounts for the paired nature of the data sets. In this case, the paired data sets are the responses to questions about the foot shroud concept and the bladder concept. However, since each question was not required to be answered when respondents were filling out the survey, all respondents who did not answer both sets of questions regarding both concepts were not used.

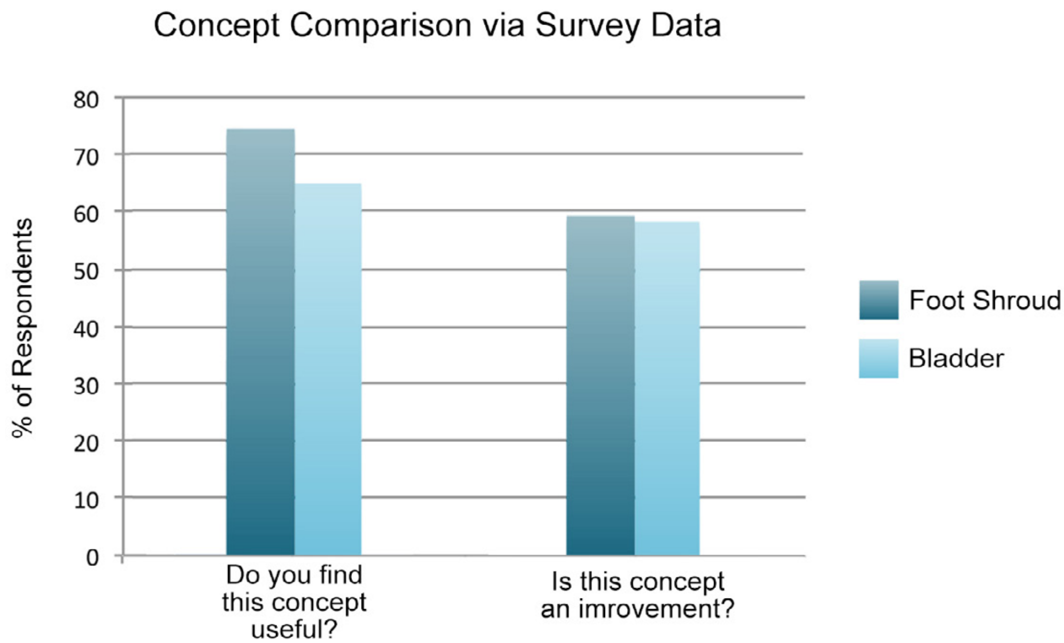


Figure 19: Graph comparing responses to concepts

The result of using McNemar's Test is a p-value. The p-value can be viewed as a measure of evidence that there is a similarity or difference between the paired data sets. A p-value of 0.05 is used as the cutoff for significant difference between the data, where any p-value below 0.05 indicates a significant difference and any p-value above 0.05 indicates a significant similarity between the paired data sets. For the question regarding whether or not respondents saw the concepts as being useful, the p-value was found to be 0.3588. For the question regarding whether or not respondents saw the concepts as being an improvement to what is currently available on the market, the p-value was found to be 0.7893. Given the results from McNemar's Test, it can be concluded that both concepts warrant further exploration due to the similarities in the data sets. Therefore, prototypes of both concepts were developed.

3.7 Prototyping

Prototyping of the two designs involved two disparate approaches. For the foot shroud, 3D models of the design were created so it can be 3D printed. There are two materials being used for the 3D printing of these prototypes. One material is Carbon Fiber PLA made by Proto-Pasta and NinjaFlex Semiflex Filament. These two materials were selected for the unique properties they possess. With Carbon Fiber PLA, printing is as easy as with other PLA materials, but it possesses greater rigidity. Furthermore, it is significantly less costly than other comparable 3D printable carbon fiber materials. NinjaFlex is a relatively new material, as are most flexible 3D printing materials. This material was selected because it is one of the least problematic flexible materials to print; it is able to repeatedly retain its shape even after a heavy load is applied to it.

A company specializing in creating a liquidized gel material was contacted for industry insight into how to produce the viscous, fluid-filled bladder concept. The liquidized gel is a lightweight gel used in cushioning for things such as water sports, motorcycles, and wheelchairs. To make these cushions, the liquidized gel manufacturer uses radio frequency (RF) welding because it creates a durable seal that is superior at preventing leaks or holes. For the material of bladder itself, polyurethane is used, as it is durable enough to withstand repeated pressure and strain and is commonly used in RF welding. For prototyping purposes, less durable and more inexpensive materials such as heat sealable nylon and heat sealable vinyl coated polyester will be used to determine the appropriate shape.

3.7.1 Early Stages of Prototyping

3.7.1.1 Foot Shroud

For the foot shroud concept, two test blocks of each material were created to determine their properties, most notably with the NinjaFlex, as the carbon fiber PLA's behavior was more predictable.

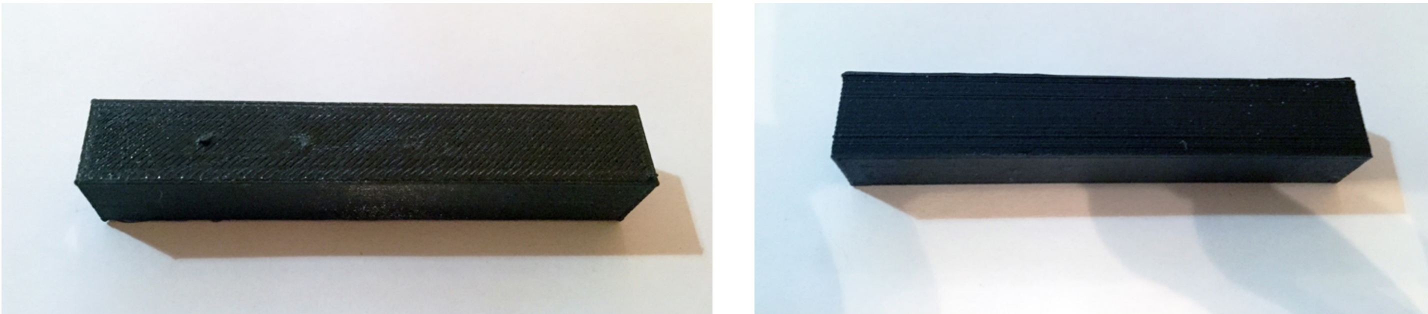


Figure 20: Test blocks of material with NinjaFlex on the left and the carbon fiber infused PLA on the right

Creating these test blocks led to a better understanding of both materials in terms of how they react to various forces applied to them. It was particularly interesting to see how the NinjaFlex material reacted because it would retain its original shape even when the block was bent and twisted at the same time. Given that a large portion of the foot shroud concept would be created using this material, this realization was very valuable. A 3D model was created of the upper portion of the shoe for the purpose of being printed with the NinjaFlex.

Figure 21: The model of MakerBot used for prototyping (left) [25] and a photo of an unsuccessful print of the foot shroud concept

As the model began to print, it was noted that the 3D printer had difficulty with the overhangs of the design. This is not an uncommon problem when 3D printing any design with an overhang, but it was especially difficult when using the NinjaFlex material. Modifications were made to the 3D model, such as reducing the draft angle and making the walls thicker. Despite making these modifications, the 3D printer was not able to handle printing such a flexible material with large overhangs. It was decided a new design of the upper portion of the foot shroud was required. While there are limitless possibilities in terms of aesthetics, the new design must be guided by the materials being used. Other designs were examined that have used 3D printed flexible materials as a source of inspiration.

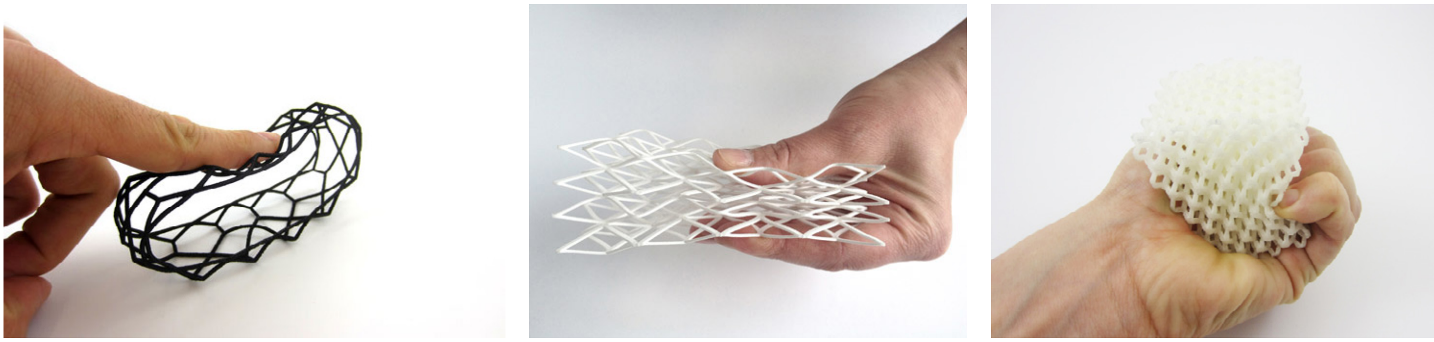


Figure 22: Examples of flexible materials used with 3D printing (in order from left to right [26], [27], [28])

After reviewing current flexible 3D printed designs, a pattern emerged. It was noted that many of the designs utilized geometric or tessellated patterns and negative space to allow for flexing. Therefore, a test print was done using a simple geometric pattern.

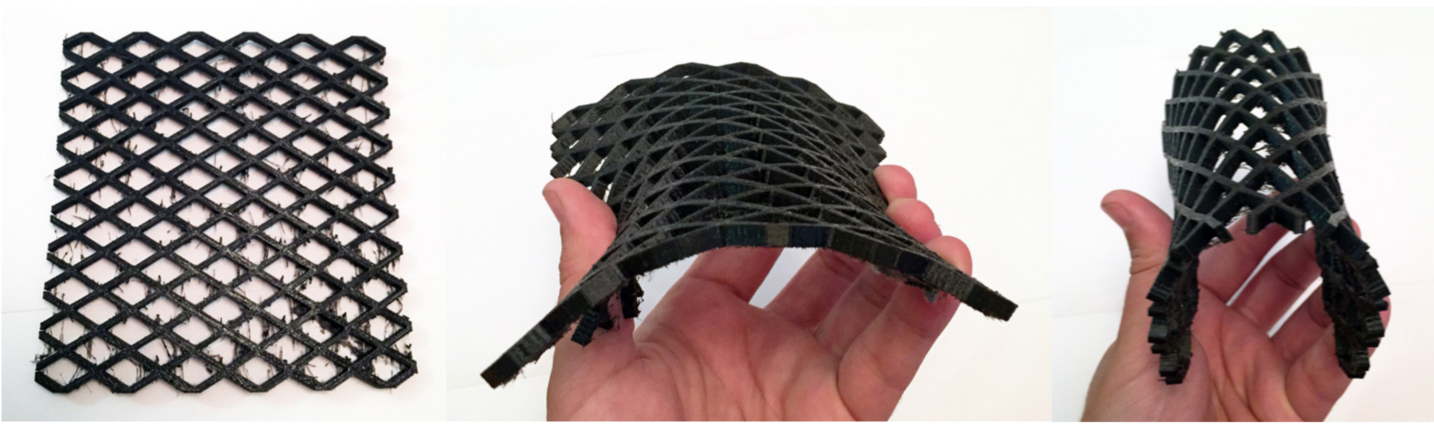


Figure 23: Test print of simple geometric pattern demonstrating its properties

This test print revealed some interesting properties such as having different levels of resistance depending on which direction force was applied, all while being able to retain its shape. Despite that the test print produced interesting results, there still remained one major issue with the design. That issue is the combination of the flexible NinjaFlex with the rigid carbon fiber PLA. Design changes can be made in order to connect these two materials, such as different connectors and fasteners. However, new 3D printing technologies needed to be consulted as changes within the industry change rapidly and frequently. One new technology investigated is the printing of two different materials simultaneously across a gradation.

A company named PolyJet claims to have, “the first technology that enables simultaneous jetting of different types of model materials” [29]. These multiple materials can differ in different aspects such as color, stiffness, and texture. Researchers at the University of Southern California discovered new method of 3D printing called mask-image-projection based stereolithography (MIP-SL), allowing material gradients are achieved in three-dimensions rather than two [30]. The design of the foot shroud concept would greatly benefit from being able to be printed in a gradation of materials or even two different materials in the same job. However, these technologies are either not available commercially in a cost-effective manner or are so new, they do not exist outside of a laboratory yet. Due to the issues associated with the production of a 3D printed foot shroud and the fact that technologies that would benefit this process are not yet commercially available, it was decided this concept was not feasible for production and was therefore ruled out as an option.

3.7.1.2 Bladder

With the bladder concept, the most important aspects to consider when prototyping are the shape of the bladder and the materials used. Up until this point, the shape used for the final design had existed only in a digital format and some paper cutouts used for dimensioning purposes. The first prototype utilized the shape from the final design and was created using sheets of polyurethane and the fluidized gel. Different adhesives were used to create a good seal; however, nothing seemed to work correctly. The first prototype was a hodgepodge of different glues and electrical tape holding two pieces of polyurethane together.

Figure 24: Initial “crude” prototype of bladder concept

As one can see from Figure 24, the focus was on functionality rather than aesthetics. The first prototype was placed in between a prosthetic foot with a pylon attached and a hiking boot (see figure 25 below). It was noted that when force was applied to the pylon in a similar manner that it would experience while the user was walking, the bladder performed as intended by allowing almost no movement of the prosthetic foot while inside of the shoe. In the same scenario without the bladder, the heel of the prosthetic foot moves up and down and side to side. Despite the positive results from this first prototype, the materials and sealing issues presented another set of problems. Therefore, different materials and adhesives needed to be tested with each other to determine which combination provided the strongest seal.

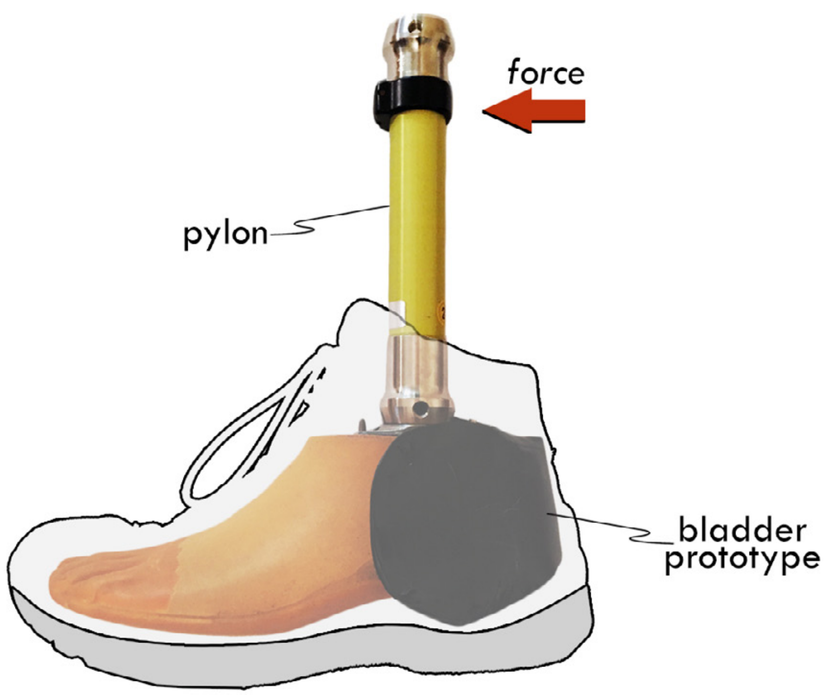


Figure 25: Diagram showing how prototypes were tested to see if they held the cosmetic shell in place

Three materials and four adhesives were tested with each other. The three materials were polyurethane, vinyl, and vinyl coated polyester. The four adhesives were contact cement, PVC/ABS cement, 3M 90 High-Strength Spray Adhesive, and Goop contact adhesive and sealant. Two pieces of each material were cut out and glue was applied around three sides of each piece. The pieces were then placed on top of one another, creating a pocket, and weight was added to ensure an even seal. The next day, each one simply had a finger placed inside the pocket and the finger was bent to see how well the seal was. Each combination of material and adhesive failed when minimal pressure was applied to them. Because of these results, new materials and sealing processes had to be explored for the prototyping phase.

After researching ways of sealing plastics and different products with similar requirements, such as the Camelbak Hydration Pack, it became clear that heat-sealing plastics was a common industry standard to reach the desired effect. Two kinds of heat sealable materials were obtained, Heat Sealable 70 Denier Nylon Taffeta and 18 oz Vinyl Coated Polyester. Both materials went through the same process as the other test materials did by creating a small pocket out of each, but this time they were heat-sealed with an iron. Both materials sealed well and each pocket was able to withstand a great deal more force than any other material or adhesive. Now that a feasible material and method of sealing was established, the focus of the prototype became the shape of the bladder.

With the first prototype, the shape was designed in such a way that it would fill in the space between the arch of the foot and the boot and between the lateral and medial malleolus and the inside of the boot.

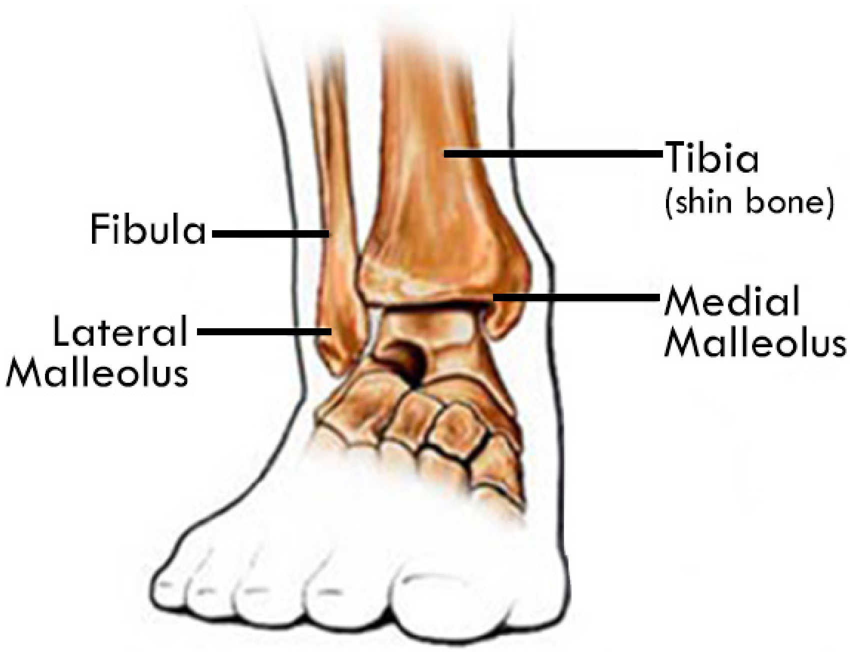


Figure 26: Diagram showing the anatomy of a human foot. Noted are the lateral and medial malleolus, which are areas of the foot needing to be considered when designing the next prototype [31]

Cosmetic shells of prosthetic feet do not have the exact anatomy of a regular human foot and are at a lower fidelity of detail. This meant that focusing a portion of the design on the arch of the cosmetic shell was no longer necessary. Furthermore, cosmetic shells vary in shape and size just like a grouping of regular human feet would. With this prototype, the areas around the lateral and medial malleolus were addressed in terms of keeping them stable, however the area around the back of the heel was not. This was due to the fact that there was not a separate reservoir for that portion of the bladder and when applied inside the shoe, the liquidized gel would be forced to either end of the bladder. This was an issue needing to be addressed in future designs. Additionally, the issue of donning and doffing the prototype was still present due to the rigid nature of the material used. Therefore, a redesign based on this prototype was required to address these issues.

3.7.2 Final Direction and Reasoning

For the final prototype, there were a few issues still remaining to be solved, including the ease of donning and doffing the device and effectively covering all areas of the cosmetic shell, including the back of the heel. New designs were created, starting with the sketches show in Figure 27.

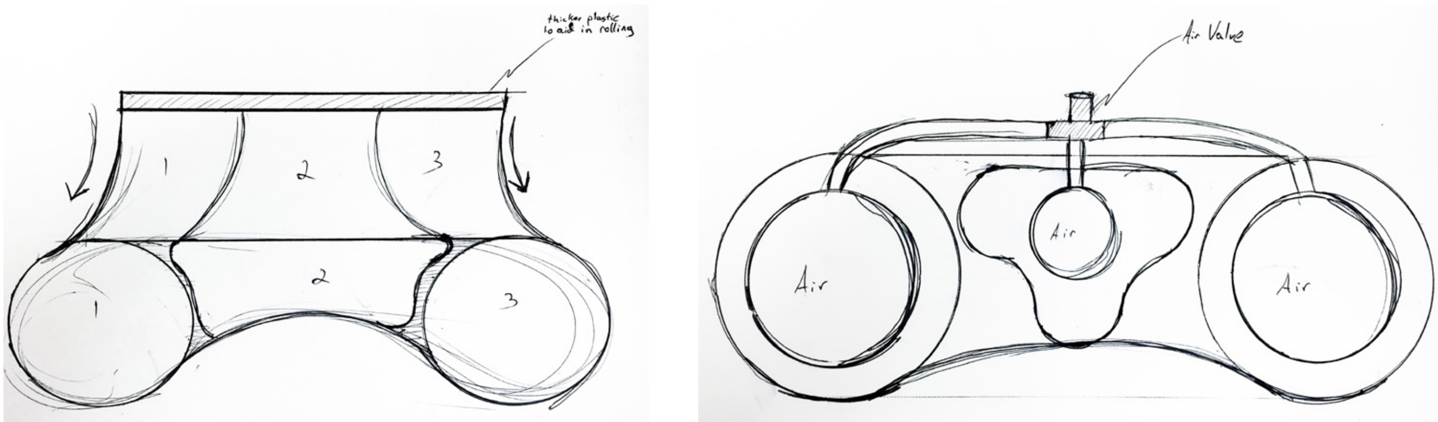
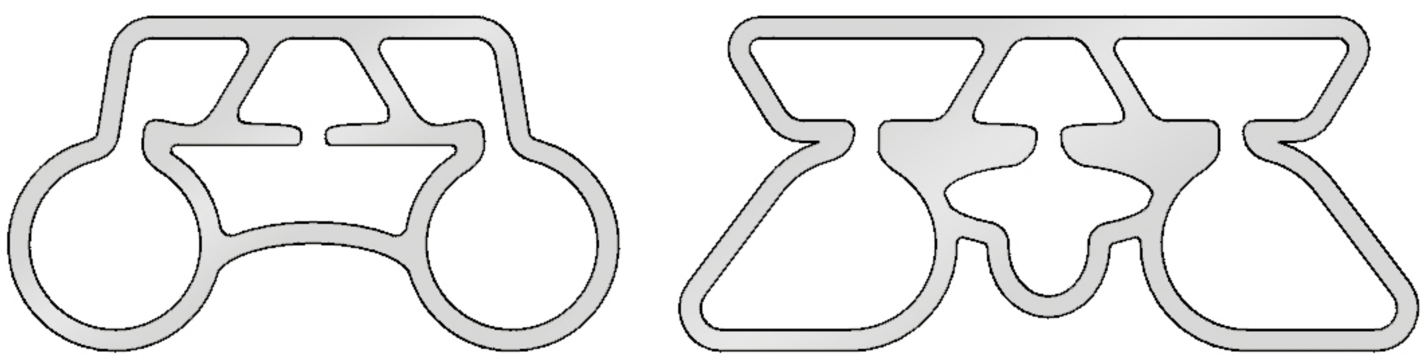


Figure 27: New designs were created to address the shortcomings of the previous prototype

The simplicity of these designs factor into solving other issues in terms of function and manufacturability. Furthermore, these designs address the issue of ease of donning and doffing by utilizing a series of reservoirs. It was determined that one way to easily don and doff the prototype was for it to inflate after the foot was put inside the shoe. Prior to donning, much of the fluidized gel will fill the top reservoir, leaving the main reservoirs more or less empty and making it easier to put the device on.

Now that a general, simplistic shape and function of the bladder had been established, a final prototype could be made. The process of RF welding was used to create the final bladder design, facilitated by the creator of the liquidized gel and a manufacturer they work with who specializes in RF welding. The tool created for RF welding is a die cut out of solid aluminum that utilizes the negative space of the die to create a bladder. A 3D model was created of two different designs to be used, Design A and Design B, as shown in Figure 28.



Design A Design B

Figure 28: Image showing the tools to be created using two different designs

Two different designs were created, Design A and Design B, to determine which shapes performed best in terms of what areas of the foot they cover. A 48” x 6” x .5” piece of multipurpose aluminum was used for the dies for RF welding. Each design was cut out twice to achieve a total 1” thickness, as required for the RF weld. The pieces were cut using a water jet cutter and then welded together, shown in Figure 29 are the dies freshly cut and before they were welded together.

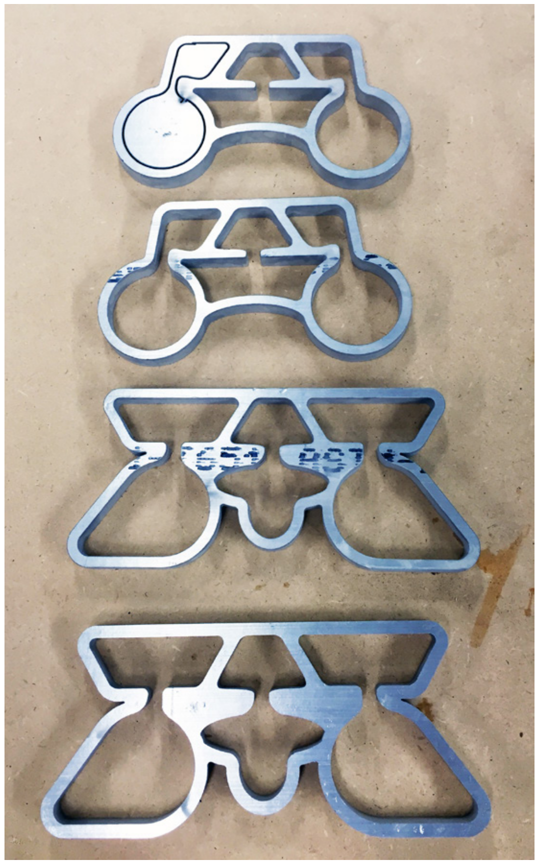


Figure 29: Image of the dies cut using a water jet cutter prior to being welded

The tools created were then sent to the RF welding manufacturer for the bladders to be created. For the first round of prototypes sent back, it was requested that two sets be created with varying levels of fill volume. The level of fill volume was not specified; it only required one to have more of the fluidized gel than the other. When the prototypes were received from the manufacturer, it was very apparent that the prototype with more of the fluidized gel was more effective at filling in the voids of a shoe. Both prototypes can be seen in Figure 30.

Figure 30: 1st round of prototypes received from he manufacturer

The same previously used simple test was performed, applying the prototype to a solid ankle cushion heel (SACH) foot and then put the foot inside of a shoe and apply force to the pylon. Design B was more effective at creating a better fitting shoe due to the fact it took up more surface area of the foot, including the arch. However, the liquidized gel did not flow well from the reservoir to the main chamber and vice versa due to the viscosity of the gel itself and the small size of opening between the two chambers.

Figure 31: Image showing how the prototypes fit onto the foot

A new set of prototypes was created with a few changes based on the testing results. After discussing what was learned with the manufacturer, it was discovered that they create different viscosities of the liquidized gel. It was decided that a lower viscosity gel would work better with the design. Only Design B was prototyped in three versions: one filled to capacity, one at 75 percent fill, and one at 50 percent fill. The simplistic design of the final prototype led it to be cost-effective for mass manufacturing. If a production run were done of 50-100 units, the cost of materials and labor per unit would come out to $5.10 without including shipping costs. This figure falls well below the result from the first survey where a majority of respondents stated they were willing to pay $250+ out-of-pocket for a prosthetic foot that aids in performing an activity. Despite the fact the previous question was speaking about a foot specifically, the figure still shows what people are willing to pay out-of-pocket in order to better perform physical activities. With the final prototype complete, a collection of sequence of use images was created and can be seen in Figure 32 on the following pages.


Ensure the top reservoir is filled to capacity by
squeezing the bottom reservoirs


Place ankle brace that contains the bladder on the cosmetic shell
Place sock on cosmetic shell


Loosen shoe and insert prosthetic foot

Tie the shoe tightly

Squeeze each individual reservoir so that it
fills the bottom reservoirs

Once each top reservoir has been emptied, stow the empty reservoir
in the remaining portion of the shoe or let it hang out.

Figure 32: Images showing the sequence of use for the final prototype

3.8 Human subject testing protocol

3.8.1 Final Design Feedback Research Protocol Description

This protocol sought to evaluate a prototype using human subjects as they traverse uneven terrain. Data collected included time it takes to traverse a simulated uneven terrain, the number of steps taken, and self-reporting from the subjects as to whether or not they could tell when they were wearing the device and their opinions on the performance of the device. The time it takes to traverse the simulated uneven terrain and the numbers of steps taken were used as data collection methods due to walking speed being a common method used in previous studies [32]. Measuring these two constructs derives one's walking speed because each participant is traversing the same distance throughout testing. Therefore, the less time it takes for a subject to traverse the simulated uneven terrain, the higher the walking speed. Furthermore, the number of steps is recorded because the number of steps taken by a subject translates directly to the stride length when traversing equal distances, which in turn relates to the walking speed [33]. The fewer steps taken by a subject during testing translate to an increase in the subject's walking speed.

3.8.2 Recruitment

This study recruited at least three, but no more than 10 subjects. Subjects were identified through Rob Kistenberg, co-director & coordinator of the prosthetics MSPO program at Georgia Institute of Technology, as lower-limb amputees have worked directly with him in the past. Only subjects who consented to being contacted from previous studies were contacted via email and asked if they would like to participate in another study. If the subject stated willingness to participate after reviewing the project outline, further details were given in regard to date, time, amount of reimbursement, and other specific details regarding the project. Willing subjects were asked a series of questions to determine whether they meet inclusion criteria and to determine their ambulatory ability. The series of questions used came from The Activities-specific Balance Confidence (ABC) Scale as it determines if potential subjects were a fall risk, and therefore suitable to participate in this study [34]. The ABC Scale uses 16 hypothetical scenarios that all begin with, "How confident are you that you will not lose your balance or become unsteady when you..." Subjects are asked to give their responses for each question in the form of a percentage, with zero percent being no confidence and 100 percent being total confidence. A copy of the initial ABC questionnaire can be found in Appendix C. Once all questions were answered, they were totaled and a percentage was determined and translated to different functional levels:

- 80% = high level of physical functioning
- 50-80% = moderate level of physical functioning
- < 67% = older adults at risk for falling; predictive of future fall
- < 50% = low level of physical functioning

Given the above assessment standards given by the ABC Scale, anyone scoring below a 67 out of 100 is a fall risk; therefore, subjects were disqualified if they scored less than 67 [35]. If subjects scored at or above a 67, they were considered for this research session.

3.8.3 Procedures

Once a group of suitable test subjects was found and scheduling was agreed upon, testing began. Before testing either prototype, subjects were asked a series of questions based on the ABC Scale. This version of the ABC Scale differed from the original version that was used to determine if potential subjects were a fall risk. The main difference is it will be centered on assessing the subject's balance, confidence, and most difficult tasks they encountered when walking over uneven terrain. Gathering this information prior to testing served as the control data to be weighed against the results. This version of the ABC Scale was also used for the questions during testing in regards to the prototype being tested. Once background information was gathered, testing began.

Figure 33: The simulated uneven terrain set up for testing

Subjects were asked to walk with their everyday prosthesis over a test course that simulates uneven terrain in order to gain the control data. The test course was constructed with boards of solid wood and panels of MDF (particle plywood) to mimic obstacles commonly encountered while hiking. These common obstacles include going up and down grades, side slopes, and obstacles such as tree roots, rocks, and branches. The side- slope portion of the test course has a slope of 5 percent in accordance with the Forrest Service Trail Accessibility Guidelines put out by the United States Forest Service [36]. The test course was situated between parallel bars affording subjects with the ability to grasp the bars to maintain balance. A prosthetist or physical therapist supervised this activity. The prosthetist was available to make adjustments to the subject's prostheses, if needed.

While walking over the test course, the subjects were timed once they have set foot on the simulated uneven terrain. The number of steps they took was recorded. After the subject walked over the simulated uneven terrain in one direction, they were asked to turn around and walk the opposite direction. Again, the subject was timed and number of steps was recorded. Once the subject completed walking over the test course, they were given 2 minutes to rest. Subjects were then asked questions (see Appendix D) from the modified ABC Scale centered on walking over uneven terrain. After this control data was obtained, the prototypes were tested using the same procedure.

The subjects then evaluated the bladder concept. Subjects were asked to remove their prosthesis so that blind testing could be done. The prosthetist took the bladder into another room and either inserted the device into the subject's shoe or left the prosthesis and shoe unmodified. A coin flip randomized the choice. This ensured that the subjects were unaware if they were using the bladder prototype or not. The prosthetist returned with the subject's prosthesis and asked the subject to don it before testing. Subjects were then asked to walk across the test course as before and were given 2 minutes to rest. The same set of questions asked for the control data were asked again.

Subjects then had their prosthesis removed a second time and taken into another room. Depending on which randomized situation was first tested, the bladder prototype was either removed or attached to the subject's prosthesis. The prosthetist then reattached the prosthesis to the subject. Subjects were then asked to walk across the simulated uneven terrain, while being timed and number of steps recorded, and then back to the start. Subjects were given 2 minutes to rest. The same set of questions asked for the control data were asked again. Because the user is unaware of which trial they are wearing the device, the feedback given will be more concise and honest, much like the placebo effect used when testing new pharmaceuticals. The prototype was then shown to the subject, and they were given an explanation as to how it functions.

Subjects were then asked to don and doff the shoe outfitted with the device and were then asked a series of questions (see Appendix E) in relation to ease of use, again in the form of an interview. Approval from the IRB at Georgia Tech was procured for human subject testing prior to the start of any trials.

CHAPTER 4

Results

4.1 Testing results

There were a total of six participants (five males and one female) for this study with an average age of 53.5; three were below- knee amputees, and three were above-knee amputees. The first subject tested followed the protocol as stated above in section 3.8.3; however, certain changes were made to the protocol following testing of this subject. Those changes were as follows:

- The protocol stated that subjects would be asked a series of questions from a modified version of the ABC scale titled “Questionnaire for Lower-limb Amputees Pertaining to Walking Over Uneven Terrain” after each round of testing. It was determined these questions only needed to be asked after the control test and after the blind test portion had been completed.
- In addition to changing the number of times subjects were asked questions from the “Questionnaire for Lower-limb Amputees Pertaining to Walking Over Uneven Terrain,” subjects were asked an initial yes or no question of “Could you tell in which round of testing you were wearing the device?” after the last round of testing. This was done because if the subject answered “no” to this additional question, then it made asking the same questions as before a moot point. If the subject answered “yes” then the same questions as before were asked and the results were compared.
- When subjects were shown the device and asked to don and doff it, an additional step was added. That step was after the subject had donned the device, they were asked to walk around the testing area, both on the simulated uneven terrain and the flat ground. This was done to drive the discussion that would come after the “Donning and Doffing Questionnaire” to ensure the subject knew what it felt like, if anything, while they were wearing the device.

With these changes made to the protocol, the other five subjects could now be tested. It should be noted that the first subject’s data was not thrown out as the same data was gathered for him or her as it was for the remainder of the subjects.

4.1.1 General observations

After testing had concluded, the observations made and comments received from discussions showed some correlation among the subjects. Some general comments received from discussions with the test subjects are as follows:

- The test course was too short to determine whether or not the device had any effect
    - Subject 004 stated, “I understand the concept of it, but I’m not sure the amount of walking on the obstacle course is enough to tell”
- Half of the participants stated that they never had a problem with the prosthetic foot moving inside the shoe while walking
- Over half of the subjects stated it is easier to change to a different prosthesis rather than changing your shoe
- The device did not hinder any movements
- The viscous fluid from the bottom reservoir would sometimes find its way back into the top reservoir while in use, indicating a need for a design change
- Going down hill is the most significant barrier faced by lower-limb amputees when traversing uneven terrain.
- Subjects 001 and 004 could tell when they were wearing the device, however Subject 004 did not report a positive difference in their walking while wearing the device
- Subjects 002, 003, 005, and 006 could not tell when they were wearing the device and therefore, could not be asked the 2nd round of the Uneven Terrain Questionnaire

- Subjects 001 and 006 reported a positive difference in their walking while wearing the device
  - Subject 001 stated, “This makes the show perform like a shoe”
  - Subject 006 stated, “This eliminates the need to make adjustments to my prosthesis when I buy a new pair of shoes”
  - Both Subject 001 and 006 were below knee amputees

Figure 34: Test subjects traversing the uneven terrain (left, middle), test subject donning the device (right)

4.2.1 Empirical results

Results for each subject are as follows:

Subject	Control		1st Trial Data			2nd Trial Data		
	steps	time	proto?	steps	time	proto?	steps	time
001, BK	26	27.66	**yes**	20	22.17	no	20	19.46
002, AK	14	12.39	no	15	12.23	**yes**	14	11.01
003, BK	17	11.45	no	16	10.23	**yes**	17	10.34
004, AK	22	24.09	no	23	23.49	**yes**	23	22.34
005, AK	29	30.98	**yes**	27	22.59	no	29	25.96
006, BK	17	13.29	no	21	16.15	**yes**	19	14.02

Figure 35: Chart depicting the test results from all 6 subjects for all trials

	Control		With Prototype		Without Prototype	
	steps	time	steps	time	steps	time
Averages	**20.83**	**19.98**	**20**	**17.08**	**20.67**	**17.92**
Std. Dev.	***5.34***	***7.87***	***4.16***	***5.41***	***4.64***	***5.67***

Figure 36: Chart depicting the averages and standard deviations of the results from Figure 35, broken down by whether or not the subject was wearing the prototype or not, along with the control data

From these results, it can be derived that the device neither helped nor hindered the subjects while they traversed the uneven terrain. Subjects 002, 004, 005, and 006 all showed some sign of improvement when wearing the device as compared to when they were not wearing the device. However, the level of improvement was negligible as the difference in value between those two constructs was less than 1 step and less than 1 second. The averages and standard deviations were also found for the data and again, demonstrated the device neither helped nor hindered the subjects while traversing the uneven terrain. The standard deviations demonstrated there was a wide range of data received from the subjects and that the data was not consistant.

Test	Average Score
ABC Test	95%
1st UTQ	95%
Don/Doff	93%

Figure 37: Chart depicting the average scores of various questionnaires used during testing.

Figure 37 demonstrated that the participants are confident in performing both day-to-day activities and activities involving uneven terrain by responding with an average score of 95 percent for both the “ABC Questionnaire” and the “Questionnaire for lower-limb amputees pertaining to walking over uneven terrain.” In response to the “Donning and Doffing Questionnaire” (see Figure 37), an average score of 93 percent was received, meaning that respondents found the device easy to don and doff. In regards to Figure 36, due to the negligible difference in the averages of the values concerning number of steps taken and time it took to complete the course, less than 1 second and less than 1 step respectively, the most appropriate conclusion is that the device neither helped nor hindered function while traversing the simulated uneven terrain. This could be due to the lack of sensitivity with the test, meaning that the test was not able to discern the difference between these two constructs due to the low number of subjects and because the obstacle course was not challenging or long enough.

Furthermore, a one-sided Wilcoxon Signed-Rank test was used to determine specifically if the amount of time and steps were significantly less when wearing the prototype as opposed to not wearing the prototype. The results from this test gave a p-vale of 0.1326 for the number of steps taken and a p-value of 0.2008 for time. Any p-value below 0.05 is considered significant; therefore there is not a significant statistical difference between the time and step values for when the subject was wearing the prototype as opposed to not wearing the prototype.

4.2 Cost comparison and analysis

A goal of this thesis was to develop a cost-effective device that aids lower-limb amputees in performing an activity. Previous results demonstrated that the device neither helped or hindered function while traversing the simulated uneven terrain, however this could be due to the lack of sensitivity with the test and the small sample size used. Nevertheless, the device did accomplish the goal of being cost-effective to the end user, as demonstrated in Figures 38 and 39.

Component	Manufacture Cost
Bladder	$5.10 (50-100 units)
Ankle Brace	$7.00 (individual)
Velcro	$0.16 (7)
Total	**$12.26**
Retail Price	**$24.52 (50% markup)**

Figure 38: Table showing the cost breakdown of the final prototype for both manufacturer and retail

Product	Type of Device	Manufacturer	Retail Cost
Kinterra Foot	prosthetic foot	Freedom Innovations	$6,359.92
Forearm Crutches	assistive device	Lofstrand	$155 per pair
Trekking Poles	assistive device	REI	$129 per pair
Stomper	prosthetic foot	Stomper Products Inc.	~$200 per unit
“Stuffing” Socks	clothing	Hanes	$0.99 per pair
Final Prototype	orthotic	Mark Husack	$24.52 per unit

Figure 39: Comparative product chart showing product information, including retail cost (From left to right; [37] Kinterra Foot, [38] forearm crutches, [39] trekking poles, [40] Stomper, [41] Hane’s Sock)

In figure 38, the three main component's prices were compared, added, and a retail cost was determined by applying a standard 50% markup to reach a retail price of $24.52. In Figure 39, the products compared all came from the comments section of the various surveys that were distributed throughout the process. Each product was described by a respondent as something lower-limb amputees currently use when traversing uneven terrain. In regard to the trekking poles, a specific model was chosen based on the top 10 selling models on a popular outdoor gear website. Those top 10 sellers' prices were averaged and the model that fell closest to that average was used for the comparative product chart. All prices are presented as retail costs; however, it should be noted that the price for the Kinterra Foot is the amount Medicare would be billed once purchased as this is an accurate representation of how this foot is normally purchased.

Figure 39 demonstrates that the final prototype falls well below the cost of many products that are used by lower-limb amputees when traversing uneven terrain. Furthermore, results from the first survey (see Figure 1) showed the majority of respondents (60.4%) were willing to pay $250 or more "out-of-pocket" for a device that aids in performing a specific activity. The retail price of $24.52 is less than 10% of what lower-limb amputees said they are willing to pay "out-of-pocket." While the device does cost more than some "home remedies", such as stuffing socks into the shoe for a better fit, it can be inferred that the device is more effective at performing its objective due to the fact the device is consistent in how it performs. It is more difficult to compare the efficacy of the device to the other retail products as they perform different functions. Lower-limb amputees do not have to purchase any kind of specialized footwear in order to use this device. For the human subject testing, subjects were asked to wear whatever shoes they felt most comfortable with wearing when traversing uneven terrain. This was done because buying a new pair of shoes for a lower-limb amputee is not a simple task. Adjustments may have to be made by a prosthetist if the heel of the new shoe varies a great deal from what the amputee was wearing when the adjustments were first made. The final prototype was designed for any kind of walking shoe, sneaker, or hiking boot that a lower-limb amputee may wear while traversing uneven terrain. Not having to purchase a specific type of footwear in order to use this device allows the retail price of $24.52 to remain as is. Furthermore, the device can be used to help imporve the fit of other types of footwear, ones that are not used for traversing uneven terrain. Because of this low cost to lower-limb amputees in relation to other products currently used when traversing uneven terrain, the device fills in the opportunity gap stated at the beginning of this body of research.

4.3 Overall conclusions

The results from the human subject testing were encouraging, despite the negligible differences between the data. Four out of the six subjects demonstrated increased walking speeds while wearing the prototype and traversing the uneven terrain. However, due to the negligible difference in these values mentioned above, the most appropriate conclusion is that the device neither helped nor hindered function while traversing the simulated uneven terrain. This could be due to the lack of sensitivity with the test, meaning that the test was not able to discern the difference between these two constructs. Regardless, the testing still produced positive results. Two out of the six respondents expressed great interest in the prototype and saw value in it by stating things such as, "this makes the shoe perform like a shoe" and "I think this is a wonderful idea because it eliminates the need to put a wedge in the shoes." Both of these statements are only a couple examples of the positive feedback received concerning the device. However, some concerns were raised during testing with the design of the prototype and the research protocol. These concerns will be addressed in sections 5.2 Weaknesses of Research Methods and 5.3 Design Modifications and Considerations of this thesis.

CHAPTER 5

Analysis

5.1 General Project Analysis

The goal of this thesis was to add to the current state of knowledge concerning what activities lower-limb amputees wish to perform, what specific barriers deter lower-limb amputees from performing said activities, and to develop a cost-effective device that aids lower-limb amputees in performing an activity. All three of these goals were met by determining that hiking and biking are two activities lower-limb amputees wish to perform but cannot due to an inadequate prosthesis, by determining the specific barriers lower-limb amputees associate with these activities, and by developing a cost-effective prototype that allows lower-limb amputees to better perform an activity, in this case hiking or traversing uneven terrain. Encouraging older, lower-limb amputees to be more active post-amputation is a difficult task by itself, but by introducing a cost-effective product that can help facilitate being more active will make encouraging them that much easier.

5.2 Weaknesses of Research Methods

While the research methodology used in this thesis proved to be fruitful, there were some improvements that could be have been made. For the first survey concerning what activities lower-limb amputees wish to perform, despite the fact there was sound reasoning for implementing a paper survey in person to the respondents, an electronic version of the survey would have been sufficient and may have produced more respondents, and therefore, more data. For the third survey concerning hiking prototypes for lower-limb amputees, the questions were based on how the respondents perceived the prototypes while only viewing a 2D image with a description. This proved to be difficult for some respondents to grasp as noted in the comments section of the survey, and therefore, made some of the data collected difficult to interpret.

Weaknesses concerning the human subject testing became evident after the first subject. Originally, questionnaires were to be asked after each time the subject traversed the uneven terrain. However, it became evident that it was only necessary to ask subjects after the first, control trial and then again after the last trial. An additional question was also added to the last questionnaire concerning traversing uneven terrain. The question was, “Could you tell in which trial you were wearing the device?” and subjects were supposed to answer either yes or no. If the question was answered “no,” then no further questions were asked because it rendered them null and void. Another weakness associated with the human subject testing was the length of the test course. Subjects were only given 28 feet for each trial to determine if they could tell a noticeable difference in the way they walked. For many of the subjects, this distance was not sufficient enough to determine this fact and some subjects suggested they would be able to give better feedback if they could use the prototype for a longer amount of time, even the whole day. Additionally, widening the inclusion criteria of the subjects would have produced a larger number of subjects and a greater variance of the type of subjects. While there were weaknesses in the research methodology, they were not significant enough to disrupt any of the data that was collected.

5.3 Design Modifications and Considerations

In regards to the final prototype designs, some issues became apparent during the human subject testing. The first issue was the method in which the bladder was attached to the ankle brace. The most up-to-date prototype has the bladder attached to the inside of the ankle brace with Velcro.

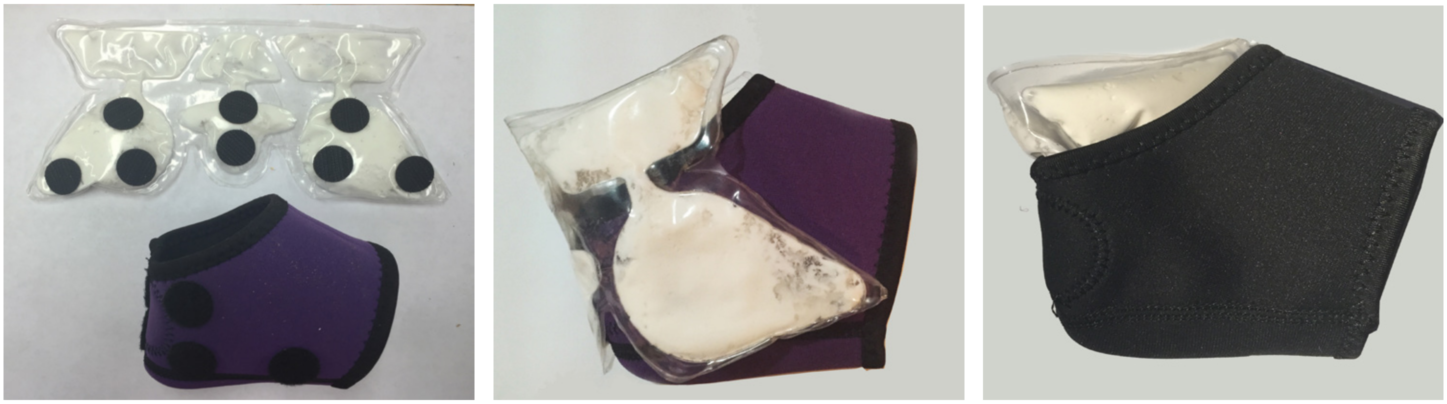
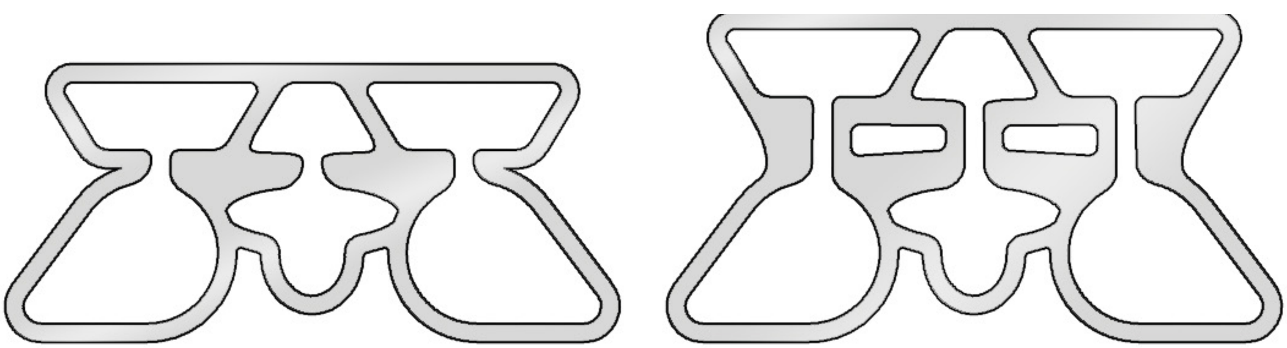


Figure 40: Images showing how Velcro was used to secure the bladder inside of the ankle brace

While the Velcro did perform as intended by holding the bladder in place, it is not a permanent solution as the connections between the Velcro are not strong enough for repeated use. A solution to this problem would be to sew the bladder into the ankle brace and allow an opening for the top reservoir.

Another issue with the prototype was the shape of the middle reservoir and its ability to cover the back portion of the heel. Because of the shape and size of this reservoir, there were issues during the RF welding process with being able to get the liquidized gel inside the reservoir. This led to less liquidized gel in this reservoir than intended and may have affected the prototype's performance. Therefore, the middle reservoir needs to be redesigned with the RF welding process in mind and have the design allow for more of the liquidized gel. The final issue was the flow between the top and bottom reservoir. As stated earlier during the prototyping process, a lower viscosity version of the liquidized gel was used to allow for better flow between the top and bottom reservoirs. However, while the prototype was in use with the test subjects, it was noted that the lower viscosity liquidized gel was being forced into the top reservoir when it should have remained in the bottom one. This did not render the prototype useless, but it also did not allow it to perform as it fully should. To remedy this issue, a design change must be made to ensure that while the device is in use, the bottom reservoir remains full and the top reservoir remains empty. A simple solution to this issue is to elongate the portion that separates the two reservoirs, allowing the top reservoir to be folded over the ankle brace and stowed with the user's sock.



Prototype design

Updated design

Figure 41: A side-by-side comparison of the tool design used for the final prototype versus the updated design.

Having this longer conduit between the two reservoirs would allow the top reservoir to be more easily manipulated in terms of stowing it in the sock while in use. Although the dimensions of this prototype were taken from averages of 20 different cosmetic shells and therefore would fit a wide range of users, different sizes may need to be created to accommodate those that did not fall within these average dimensions. This could be easily done simply by scaling the 3D model of the prototype, either larger or smaller, and then creating another tool that would be able to create a different sized bladder.

Appendix A

Hiking and Biking Barriers for Lower-Limb Amputees

Hiking and Biking Barriers for Lower-Limb Amputees

Page description:

My name is Mark Husack and I am a Masters of Industrial Design student from the Georgia Institute of Technology in Atlanta, Georgia. The purpose of this survey is to determine what barriers exist for lower-limb amputees when it comes to hiking over uneven terrain and biking or cycling. By voluntarily participating in this survey, your identity will remain anonymous and confidential as no personal information, other than your age and gender, will be given. If you choose to participate, you are free not to answer any of the given questions. If you have any questions, comments, or concerns about this study, feel free to contact me at husack.m@gmail.com or by telephone at (404) 626-0257. Thank you.

Basic Information

Page description:

1. Gender

- Male
- Female

2. Age

3. What type of lower-limb amputation do you have?

- Above Knee
- Below Knee

Hiking

Page description:

For the following questions, hiking and walking over uneven terrain are defined as any unpaved and rough surface that might be encountered while hiking on a path, walking through the woods, or walking on a stream bank.

4. Do you have any interest in hiking or walking over uneven terrain as a physical activity?

- Yes
- No

Hiking

Page description:

5. Would a better performing prosthesis or better equipment result in your wanting to hike or walk on uneven terrain? Why or why not?

Hiking

Page description:

6. Do you currently go hiking or walking over uneven terrain as a physical activity?

- ○ Yes
- ○ No

Hiking

Page description:

7. What type prosthesis and additional equipment do you currently use while hiking or walking over uneven terrain? (check all that apply)

- ☐ My regular, everyday prosthesis
- ☐ A special prosthesis designed for activity
- ☐ A special prosthetic foot designed for activity
- ☐ Regular commercial hiking boots or walking shoes
- ☐ Special boots or shoes fabricated for me
- ☐ Other ______

8. What limitations do you face while hiking or walking over uneven terrain? (check all that apply)

- ☐ Walking up/down hill
- ☐ Sense of a loss of balance
- ☐ Sense of a loss of traction
- ☐ Side slopes
- ☐ Walking over rocks or roots
- ☐ Uncomfortable socket
- ☐ Other ______

9. In your opinion, do you see a need for special equipment to improve walking on uneven terrain? (check the appropriate level of need as it relates the type of device listed)

	A prosthetic foot designed for walking on uneven terrain	A device that improves the fit and function of commercial hiking boots when worn by amputees	A special boot or shoe designed to be used with a prosthesis
Yes, I see a need	☐	☐	☐
Yes, I see a need, but not for me	☐	☐	☐
No, I do not see a need	☐	☐	☐

Hiking

Page description:

10. Why is hiking something you are interested in, but do not currently perform for physical activity? Please list all reasons below in your own words

11. Is lack of motivation a factor for you when it comes to performing a physical activty? Why or why not?

Biking

Page description:

12. Do you have any interest in biking/cycling as a physical activity?

- Yes
- No

Biking

Page description:

13. Would a better performing prosthesis or better equipment result in your wanting to hike or walk on uneven terrain? Why or why not?

Biking

Page description:

14. Do you currently go biking/cycling ?

- ○ Yes
- ○ No

Biking

Page description:

15. What type of prosthesis and additional equipment do you currently use while biking/cycling?

- ☐ My regular, everyday prosthesis
- ☐ A special prosthesis designed for activity
- ☐ A special prosthetic foot designed for activity
- ☐ Regular commercial biking shoes or regular shoes
- ☐ Special shoes or clip fabricated for me
- ☐ Other

16. What limitations do you face while biking/cycling? (check all that apply)

- ☐ Mounting the bike
- ☐ Securing prosthetic foot to the pedal
- ☐ Socket discomfort
- ☐ Poor balance on the bike
- ☐ Other

17. In your opinion, do you see a need for special equipment to improve biking/cycling? (check the appropriate level of need as it relates the type of device listed)

	A clip that secures your prosthetic foot to the pedal	A bicycle built specifically for lower-limb amputees	A prosthetic leg meant specifically for biking
Yes, I see a need	☐	☐	☐
Yes, I see a need, but not for me	☐	☐	☐
No, I do not see a need	☐	☐	☐

Biking

Page description:

18. Why is biking/cycling something you are interested in, but do not currently perform for physical activity? Please list all reasons below in your own words

19. Is lack of motivation a factor for you when it comes to performing a physical activity? Why or why not?

(untitled)

20. Is there anything else you would like to share about your feelings, experiences, or knowledge regarding hiking or biking as a lower limb amputee?

Thank You!

Thank you for taking our survey!

Appendix B

Hiking Prototypes for Lower-limb Amputees

Hello!

Page description:

My name is Mark Husack. I am a Masters of Industrial Design student from the Georgia Institute of Technology in Atlanta, Georgia. The purpose of this survey is to determine the advantages and disadvantages of two concepts for lower-limb amputees in relation to hiking. By voluntarily participating in this survey, your identity will remain anonymous and confidential as no personal information, other than your age and gender, will be given. If you choose to participate, you are free not to answer any of the given questions. If you have any questions, comments, or concerns about this study, feel free to contact me at husack.m@gmail.com or by telephone at (404) 626-0257. Thank you.

Basic Information

Page description:

1. Gender

- ○ Male
- ○ Female

2. Age

- ○ <30
- ○ 30-44
- ○ 45-54
- ○ 55+

3. What type of lower-limb amputation do you have?

- ○ Below Knee
- ○ Above Knee

4. How would you describe your current activity level?

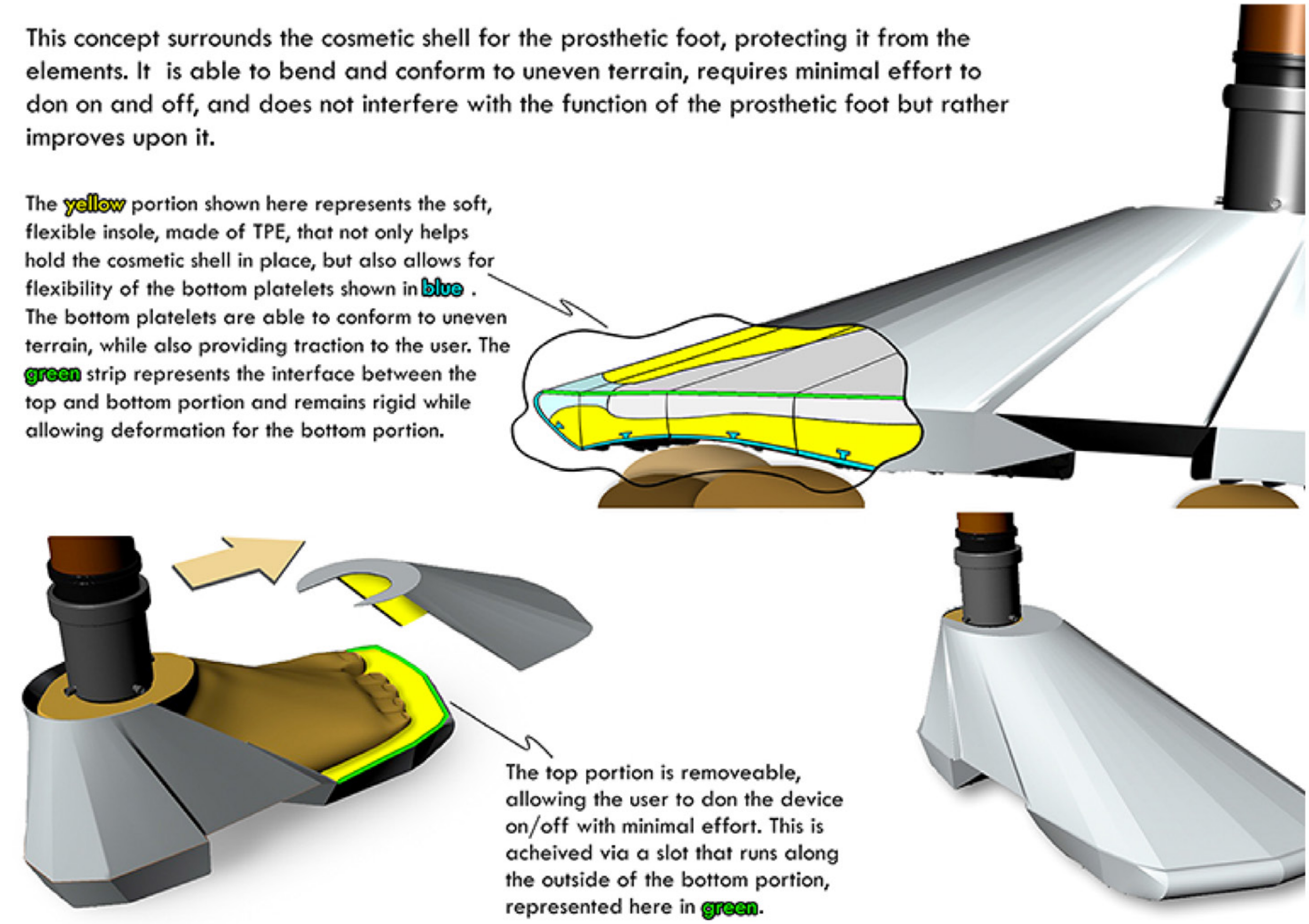
Very Active (running, high activity sports)	Somewhat Active (moderate jogging)	Not very active (walking only)	No activity (do not walk)
○	○	○	○

5. How often do you walk on uneven terrain?

Regularly	Occasionally	Rarely	Never
○	○	○	○

Cosmetic Shell Shroud

Page description:



Please review this concept page and answer the questions below.

6. How useful do you see this concept being for hiking or walking over uneven terrain?

Very useful	Somewhat useful	Not very useful	Not useful at all
○	○	○	○

7. In your opinion, rate the effort of applying and removing this device.

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
○	○	○	○	○

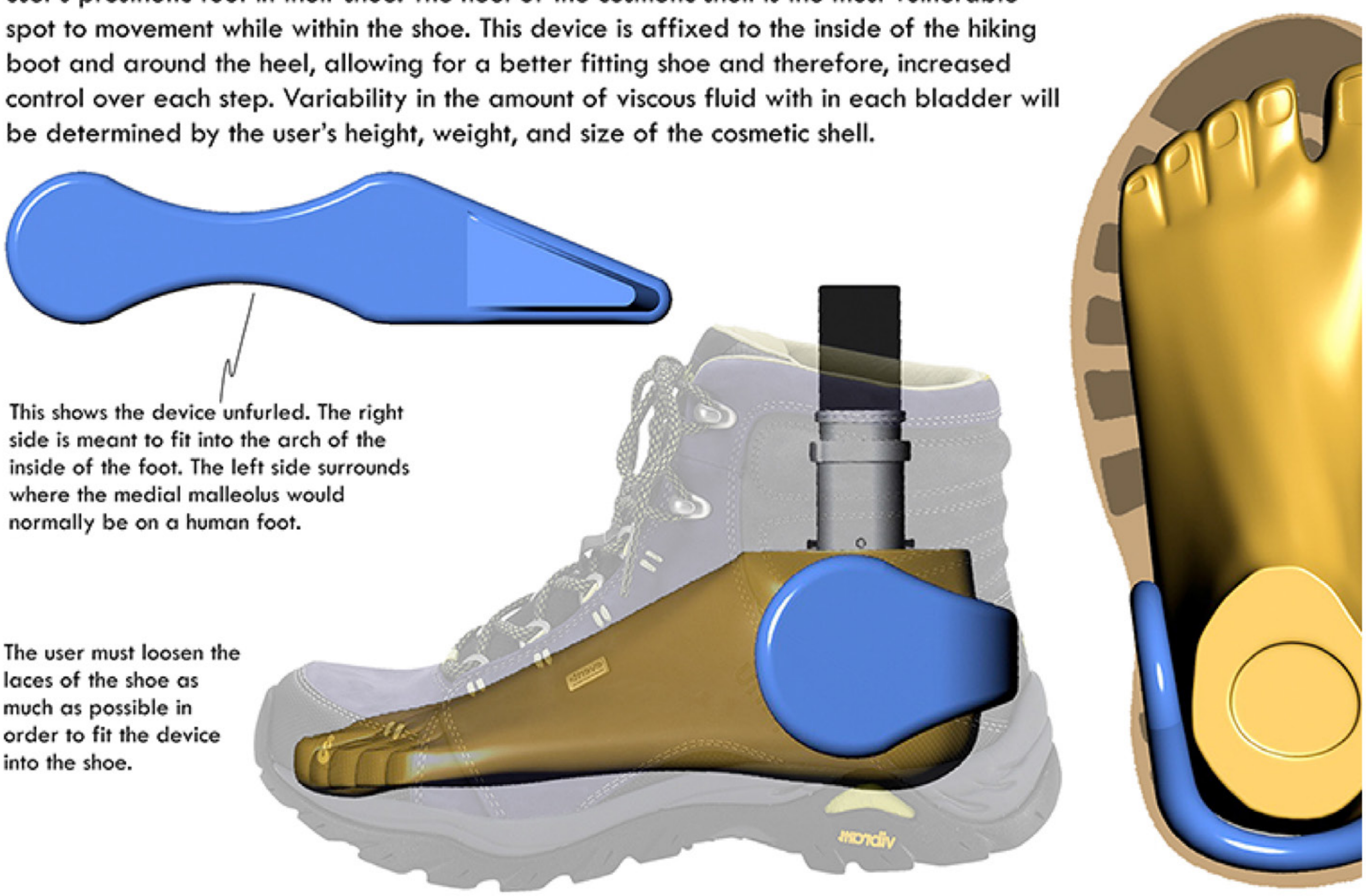
8. Rate the improvement of this device compared to what is currently availalbe for walking on uneven terrain.

Vast improvement	Some improvement	Not much improvement	No improvement
○	○	○	○

Viscous-fluid Filled Bladder

Page description:

This concept consists of a viscous-fluid filled bladder, specifically shaped to help hold the user's prosthetic foot in their shoe. The heel of the cosmetic shell is the most vulnerable spot to movement while within the shoe. This device is affixed to the inside of the hiking boot and around the heel, allowing for a better fitting shoe and therefore, increased control over each step. Variability in the amount of viscous fluid with in each bladder will be determined by the user's height, weight, and size of the cosmetic shell.



Please review this concept page and answer the questions below

9. How useful do you see this concept being for hiking or walking over uneven terrain?

Very useful	Somewhat useful	Not very useful	Not useful at all
○	○	○	○

10. In your opinion, rate the effort of applying and removing this device

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
○	○	○	○	○

11. Rate the improvement of this device compared to what is currently availalbe for walking on uneven terrain.

Vast improvment	Some improvment	Not much improvement	No improvment
○	○	○	○

Additional Comments

Page description:

12. Do you have any additional questions, comments, or concerns about either prototype?

Thank You!

Thank you for tyour feedback, it is very important to us!

Appendix C

Cosmetic Shell Dimension Chart

Cosmetic Shell	Overall Length	Overall Width	Overall Height	Heel Width (B)
(manu, L or R, size)	(longest point)	(widest point)	(tallest point)	(bottom of heel)
24L Sure-flex	23.5	7.91	8.12	6.17
24R Sure-flex	23	7.83	7.7	6.08
25R otto bock	24.7	8.34	7.81	6.05
25L Willowwood	24.5	8.51	8.1	6.02
25L Sure-flex	24.5	8.03	7.33	6.44
26L	25.5	8.51	8.23	5.85
26R otto bock	26	8.99	9.62	6.18
26L+ CPI	25.9	8.2	7.55	5.95
26L	25.5	8.45	7.32	6.37
26L otto bock	25.5	9.2	9.18	6.53
27L Sure-flex	26.7	8.49	8.24	6.26
27L CPI, ts?	26.6	8.75	9.67	6.1
28R Sure-flex	27.5	8.8	8.11	6.74
28R KT8	27.8	9.02	8.57	6.59
28L CPI, v?	28	9.66	8.14	6.84
28L otto bock	28.2	9.28	8.25	6.57
29L Kingsley	28.8	9.5	10.6	6.6
30L Sure-flex	29.5	9.69	8.64	7.43
30L otto bock	29.8	9.77	9.92	7.03
31R	30.5	8.98	8.21	6.54
Averages	**26.6**	**8.7955**	**8.4655**	**6.417**
Standard Deviation	**2.06**	**0.5812**	**0.8707**	**0.3866**
Median	**26.3**	**8.775**	**8.22**	**6.405**

Cosmetic Shell	Heel Width (T)	Arch Height	Arch Length	Fidelity(L,M,H)
(manu, L or R, size)	(top of heel)	(clearance)	(clearance-width)	low, med, high
24L Sure-flex	5.99	0.73	10.98	low, old, cracking
24R Sure-flex	6.25	0.74	10.77	med, toes
25R otto bock	6.43	0.84	11.35	med, toes
25L Willowwood	6.14	0.68	9.16	low, old, faded
25L Sure-flex	7.22	0.75	10.08	med, toes
26L	6.51	1.1	13.16	high, split toe
26R otto bock	6.07	0.73	10.83	med, toes
26L+ CPI	6.84	0.49	11.99	low, barely toes
26L	7.24	1.17	12.96	low, barely toes
26L otto bock	6.82	0.83	10.96	med, toes
27L Sure-flex	6.1	1.16	12.23	med, toes
27L CPI, ts?	6.74	1.04	14.89	med, toes
28R Sure-flex	6.67	0.97	12.88	med, toes
28R KT8	6.67	0.9	10.91	low, old, faded
28L CPI, v?	7.59	0.72	14.98	med, toes
28L otto bock	7.43	0.95	9.84	med, toes
29L Kingsley	6.17	1.57	13.24	low, old
30L Sure-flex	6.74	1.02	14.09	med, toes
30L otto bock	6	0.92	12.66	med, toes
31R	7.12	0.54	10.85	med, toes
Averages	**6.637**	**0.8925**	**11.9405**	
Standard Deviation	**0.483738**	**0.24114**	**0.501829**	
Median	**6.67**	**0.87**	**11.67**	

Appendix D

Gender_____ Age_____ Type of Amputation____ Weight____

Date of Amputation_____ English Writer/Speaker_____ ID#_001_

Instructions to Subjects:
For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100%. If you do not currently do the activity in question, try to imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports. If you have any questions about answering any of these items, please ask the administrator.

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%

<u>no confidence</u> <u>completely confident</u>

"How confident are you that you will not lose your balance or become unsteady when you-...

1. ...walk around the house? _____%

2. ...walk up or down stairs? _____%

3. ...bend over and pick up a slipper from the front of a closet floor? _____%

4. ...reach for a small can off a shelf at eye level? _____%

5. ...stand on your tiptoes and reach for something above your-head? _____%

6. ...stand on a chair and reach for something? _____%

7. ...sweep the floor? _____%

8. ...walk outside the house to a car parked in the driveway? _____%

9. ...get into or out of a car? _____%

10. ...walk across a parking lot to the mall? _____%

11. ...walk up or down a ramp? _____%

12. ...walk in a crowded mall where people rapidly walk past you? _____%

13. ...are bumped into by people as you walk through the mall? _____%

14. ...step onto or off an escalator while you are holding onto a railing? _____%

15. ... step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? _____%

16. ...walk outside on icy sidewalks? _____%

Appendix E

Questionnaire for lower-limb amputees pertaining to walking over uneven terrain

Instructions to Subjects:
For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100%. If you do not currently do the activity in question, try to imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports. If you have any questions about answering any of these items, please ask the administrator.

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0%	10	20	30	40	50	60	70	80	90	100%
no confidence										completely confident

Could you tell which time you were wearing the device? Yes No

If you were wearing the device, how confident are you that you will not lose your balance or become unsteady when your…

1. …walk over a path covered in gravel? _____%

2. …walk though the front yard of someone's house? _____%

3. …walk over a path covered in exposed tree roots? _____%

4. …walk over a path covered in loose dirt, leaves, and small rocks? _____%

5. …walk over a path that slopes from one side to the other? _____%

6. …walk over a path that has frequent dips or holes? _____%

7. …bend over to pick up an object while standing on uneven terrain? _____%

8. …bend over to pick up anything up while standing on loose soil or terrain? _____%

9. …move your upper body quickly, for example to cast a fishing line, while standing on uneven terrain? _____%

10. …sit down on a log or rock while standing on uneven terrain? _____%

Appendix F

Donning and Doffing Questionnaire

Instructions to Subjects:
For each of the following, please indicate the level of difficulty in performing the activity of donning and doffing the prototype from choosing one of the percentage points on the scale form 0% to 100%. If you have any questions about answering any of these items, please ask the administrator.

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0%	10	20	30	40	50	60	70	80	90	100%
very difficult										very easy

"How easy or difficult was it for you to...

1. ...figure out how to don the device? ____%

2. ...don the device with out any assistance? ____%

3. ...ensure the device was on your prosthesis properly? ____%

4. ...figure out how to doff the device? ____%

5. ...doff the device with out any assistance? ____%

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